

EXHIBIT 5

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MAINE**

JERE GRAY, et al.,)	
)	
Plaintiffs,)	
)	
vs.)	Civil Action No.
)	1:21-cv-00071-LEW
GOVERNOR JANET T. MILLS,)	
et al.,)	
)	
Defendants.)	
_____)	

DECLARATION OF PETER A. MCCULLOUGH, MD, MPH

Pursuant to 28 U.S.C. §1746, I, Peter A. McCullough, MD, MPH, declare under the penalty of perjury of the laws of the United States of America, and state upon personal knowledge that:

1. I am an adult of sound mind, 58 years old, and make this statement voluntarily, based upon my own personal knowledge, education and experience, and under the penalty of perjury of the laws of the United States of America.
2. I am competent to testify to the facts and matters set forth herein.
3. After receiving a bachelor's degree from Baylor University, I completed my medical degree as an Alpha Omega Alpha graduate from the University of Texas Southwestern Medical School in Dallas. I went on to complete my internal medicine residency at the University of Washington in Seattle, a cardiology fellowship including service as Chief Fellow at William Beaumont Hospital, and a master's degree in public health at the University of Michigan.

4. I am board certified in internal medicine and cardiovascular disease and hold an additional certification in clinical lipidology, and previously echocardiography. I am on the medical staff at Baylor University Medical Center and Baylor Jack and Jane Hamilton Heart and Vascular Hospital, in Dallas, Texas. I am also on staff at Baylor Heart and Vascular Institute, which promotes cardiovascular research and education. I practice internal medicine and clinical cardiology as well as teach, conduct research, and am an active scholar in medicine with roles as an author, editorialist, and reviewer at dozens of major medical journals and textbooks. I am Professor of Medicine at Texas A & M University School of Medicine, Baylor Dallas Campus.

5. I have led clinical, education, research, and program operations at major academic centers (Henry Ford Hospital, Oakland University William Beaumont School of Medicine) as well as academically oriented community health systems. I spearheaded the clinical development of *in vitro* natriuretic peptide and neutrophil gelatinase associated lipocalin assays in diagnosis, prognosis, and management of heart and kidney disease now used worldwide. I also led the first clinical study demonstrating the relationship between severity of acute kidney injury and mortality after myocardial infarction. I have contributed to the understanding of the epidemiology of chronic heart and kidney disease through many manuscripts from the Kidney Early Evaluation Program Annual Data Report published in the American Journal of Kidney Disease, and participated in clinical trial design and execution in cardiorenal applications of acute kidney injury, hypertension, acute coronary syndromes, heart failure, and chronic cardiorenal syndromes. I participated in event adjudication (involved attribution of cause of death) in trials of acute coronary syndromes, chronic kidney disease, heart failure, and data safety and monitoring of anti-diabetic agents, renal therapeutics, hematology products, and gastrointestinal treatments.

6. I frequently lecture and advise on internal medicine, nephrology, and cardiology to leading institutions worldwide. I am recognized by my peers for my work on the role of chronic kidney disease as a cardiovascular risk state. I have over 1000 related scientific publications, including the “Interface between Renal Disease and Cardiovascular Illness” in Braunwald’s Heart Disease Textbook. My works have appeared in the *New England Journal of Medicine*, *Journal of the American Medical Association*, and other top-tier journals worldwide. I am an associate editor of the *American Journal of Cardiology* and the *American Journal of Kidney Diseases*. I have testified before the U.S. Senate Committee on Homeland Security and Governmental Affairs, the U.S. Food and Drug Administration Cardiorenal Advisory Panel and its U.S. Congressional Oversight Committee, and the Texas Senate Committee on Health and Human Services.

7. Since the outset of the pandemic, I have been a leader in the medical response to the COVID-19 disaster and have published “Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection,” the first synthesis of sequenced multidrug treatment of ambulatory patients infected with SARS-CoV-2 in the *American Journal of Medicine* and updated in *Reviews in Cardiovascular Medicine*.^{1, 2} I have 36 peer-reviewed

¹ McCullough PA, Kelly RJ, Ruocco G, Lerma E, Tumlin J, Wheelan KR, Katz N, Lepor NE, Vijay K, Carter H, Singh B, McCullough SP, Bhambi BK, Palazzuoli A, De Ferrari GM, Milligan GP, Safder T, Tecson KM, Wang DD, McKinnon JE, O’Neill WW, Zervos M, Risch HA. Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection. *Am J Med*. 2021 Jan;134(1):16-22. doi: 10.1016/j.amjmed.2020.07.003. Epub 2020 Aug 7. PMID: 32771461; PMCID: PMC7410805.

² McCullough PA, Alexander PE, Armstrong R, Arvinte C, Bain AF, Bartlett RP, Berkowitz RL, Berry AC, Borody TJ, Brewer JH, Brufsky AM, Clarke T, Derwand R, Eck A, Eck J, Eisner RA, Fareed GC, Farella A, Fonseca SNS, Geyer CE Jr, Gonnering RS, Graves KE, Gross KBV, Hazan S, Held KS, Hight HT, Immanuel S, Jacobs MM, Ladapo JA, Lee LH, Littell J, Lozano I, Mangat HS, Marble B, McKinnon JE, Merritt LD, Orient JM, Oskoui R, Pompan DC, Procter BC, Prodromos C, Rajter JC, Rajter JJ, Ram CVS, Rios SS, Risch HA, Robb MJA, Rutherford M, Scholz M, Singleton MM, Tumlin JA, Tyson BM, Urso RG, Victory K, Vliet EL, Wax CM, Wolkoff AG, Wooll V, Zelenko V. Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19). *Rev Cardiovasc Med*. 2020 Dec 30;21(4):517-530. doi: 10.31083/j.rcm.2020.04.264. PMID: 33387997.

publications on the infection cited in the National Library of Medicine. Through a window to public policymakers, I have contributed extensively on issues surrounding the COVID-19 crisis in a series of OPED's for *TheHill*. I testified on the SARS-CoV-2 outbreak in the U.S. Senate Committee on Homeland Security and Governmental Affairs on November 19, 2020. I testified on lessons learned from the pandemic response in the Texas Senate Committee on Health and Human Services on March 10, 2021, and on early treatment of COVID-19 the Colorado General Assembly on March 31, 2021.

8. I am a Fellow of the American College of Cardiology, the American Heart Association, the American College of Physicians, the American College of Chest Physicians, the National Lipid Association, and the National Kidney Foundation. I am also a Diplomate of the American Board of Clinical Lipidology.

9. In 2013, I was honored with the International Vicenza Award for Critical Care Nephrology for my contribution and dedication to the emerging problem of cardiorenal syndromes. I am the President of the Cardiorenal Society of America, an organization dedicated to bringing together cardiologists and nephrologists and engage in research, improved quality of care, and community outreach to patients with both heart and kidney disease.³

10. I am the current President of the Cardiorenal Society of America, a professional organization dedicated to advancing research and clinical care for patients who have combined heart and kidney disease. I am the Editor-in-Chief of *Cardiorenal Medicine*, a primary research journal listed by the National Library of Medicine which is the only publication with a primary focus on research concerning patients with combined heart and kidney disease. Finally, I am the Editor-in-Chief of *Reviews in Cardiovascular Medicine*, a widely read journal that publishes

³ See <http://www.cardiorenalsociety.org/> (last visited April 8, 2021).

reviews on contemporary topics in cardiology and is also listed by the National Library of Medicine.

11. A copy of my resume is attached to this report as **Exhibit A**, which further demonstrates my academic and scientific achievements and provides a list of publications authored by me in the past 30 years.

12. Public health officials have relied on the “polymerase chain reaction” (“PCR”) test in order to detect and report the presence of live, infectious SARS-CoV-2 virus in human beings with suspected COVID-19 illness. The PCR test requires a sample of mucus from a person’s nose or throat or sputum (and more recently, PCR tests using saliva have been introduced). The sample is searched for viral RNA, which is a fragment of genetic material belonging to a virus. RNA is then converted to DNA through a process called reverse transcription, which is then amplified many times to make it detectable, through a process called “polymerase chain reaction.” The PCR process of amplification involves creating copies of the viral DNA and is done in cycles, and the cycles can be repeated until there are as many as one billion copies of the original viral fragment. The number of times a cycle is repeated is called the “Ct value.”⁴

13. PCR tests have been shown to produce a highly elevated rate of “false positive” results in people who are likely not infectious, especially in asymptomatic (healthy) people who are being screened and have no signs or symptoms of COVID-19. This is a by-product of the PCR process, in which a viral genetic fragment is amplified in cycles. Each amplification cycle is a doubling, so it is exponential. This means that an amplification factor of 40 is 1×2 to the

⁴ Jawerth, Nicole, “How is the COVID-19 Virus Detected using Real Time RT-PCR?” International Atomic Energy Agency (March 27, 2020), <https://www.iaea.org/newscenter/news/how-is-the-covid-19-virus-detected-using-real-time-rt-pcr> (last visited April 1, 2021).

40th power, or more than a trillion times amplification. As explained in a review of PCR tests, published by the *Society of Critical Care Medicine*:

Through the use of fluorescent probes and detection steps between replication cycles, the test allows quantification of the amount of viral RNA (viral load) in a sample. As DNA is replicated exponentially during PCR, the fluorescence also increases exponentially. The [testing] instrument reports a Ct (cycle threshold), which is the number of replication cycles that are required to produce a fluorescent signal that exceeds a baseline. Samples that contain a large starting amount of viral RNA require fewer cycles to produce a detectable fluorescent signal (and therefore have a lower Ct). The Ct has a simple negative linear correlation with the logarithm of the number of viral copies in the original sample. This relationship quantifies the amount of viral RNA in a specimen; however, the assays [tests] must then include additional standards containing known concentrations of viral RNA.⁵

14. There are three important things to note in this description. One is reference to a “baseline,” a point at which viral RNA presence is deemed significant, which is determined by each SARS-CoV-2 test manufacturer, not a standard established by a centralized public health authority like the FDA. Another is that in order to quantify the amount of virus in a specimen, the test must compare the resultant “Ct value” to “some known concentration of RNA.” It is not known if the tests do this but our research indicates that the test result is simply a binary.

15. The third important point is that “the Ct has a simple negative linear correlation with the logarithm of the number of viral copies in the original sample.” The number of cycles at which viral fragment is detected varies with the viral load, or the amount of virus, that an individual is carrying. So individuals who “test positive” at a higher cycle threshold have a lighter viral load, and are therefore not likely to be infectious. Current practice is to report test results as binary results, “positive” or “negative,” with no reference to “Ct value,” and therefore

⁵ Motley, Michael P.; Bennett-Guerrero, Elliott; Fries, Bettina C.; Spitzer, Eric D., Review of Viral Testing (Polymerase Chain Reaction) and Antibody/Serology Testing for Severe Acute Respiratory Syndrome-Coronavirus-2 for the Intensivist, *Critical Care Explorations*: June 2020 - Volume 2 - Issue 6 - p e0154, https://journals.lww.com/ccejjournal/Fulltext/2020/06000/Review_of_Viral_Testing__Polymerase_Chain.22.aspx (last visited April 1, 2021).

with no consideration of how much of a viral load a person may carry or how infectious they may or may not be, grossly inflating the number of people who pose a risk to others. Also, without any standardized guidance from the FDA, the number of cycles at which a test result is deemed “positive” or “negative” varies from lab to lab, test to test. There is no standard establishing the requisite viral load for the presentation of the COVID-19 disease. There is no also no standard, or even estimate, as to what viral load would be necessary for the virus to become a danger to others. Such standards are impossible to create, because the threshold viral loads can vary substantially from person to person. Thus public health authorities relying upon the PCR tests are using “guesstimates” to make “guesstimates” to make further “guesstimates” in order to justify their policies.

16. In September 2020, the *Journal of Clinical Infectious Diseases* published scientific research supported by a grant from the French government, in which scientists performed 250,566 COVID-19 PCR tests on 179,151 patients and found that 13,161 were positive.⁶ They selected 3,790 “positive” samples and attempted to grow a live virus from these samples in a culture medium. They were only successful in growing a virus in about half of the samples. For those samples, in which the “Ct value” was 25 cycles for a positive test, 70% grew a virus. But when the “Ct value” was 35 cycles, only 3% of the samples grew a virus. This is important since many of the PCR tests granted Emergency Use Authorization by the FDA use a “Ct value” of 35-45 cycles or higher when testing for COVID-19, and at these cycles we can expect a false-positive rate as high as 97% based on the French study. The study concludes that positive test results at “Ct values” over 30 should not be used to guide public health decisions.

⁶ Jaafar R, Aherfi S, Wurtz N et al. “Correlation Between 3790 Quantitative Polymerase Chain Reaction-Positive Samples and Positive Cell Cultures, Including 1941 Severe Acute Respiratory Syndrome Coronavirus 2 Isolates.” *Clin Infect Dis* 2020 Sep; <https://doi.org/10.1093/cid/ciaa1491>.

17. In December 2020 (**Exhibit B**) and January 2021⁷, the World Health Organization (“WHO”) issued Information Notices warning about false positive PCR test results at high cycle values. The December 2020 Notice cautions: “[u]sers of RT-PCR reagents should read the IFU carefully to determine if manual adjustment of the PCR positivity threshold is necessary to account for any background noise which may lead to a specimen with a high cycle threshold (Ct) value result being interpreted as a positive result.” The January 2021 Notice calls for “careful interpretation of weak positive results” and reminds clinicians that “[t]he cycle threshold (Ct) needed to detect virus is inversely proportional to the patient’s viral load.”

18. Dr. Anthony Fauci, Director of the National Institute of Allergies and Infectious Diseases, and Chief Medical Advisor to the President, has stated that PCR tests are useless for diagnosing COVID-19 when run at 35 cycles or higher:

What is now evolving into a bit of a standard is that if you get a cycle threshold of 35 or more that the chances of it being replication competent are miniscule... We have patients, and it is very frustrating for the patients as well as for the physicians...somebody comes in and they repeat their PCR and it’s like 37 cycle threshold...you can almost never culture virus from a 37 threshold cycle. So I think if somebody does come in with 37, 38, even 36, you gotta say, you know, it’s dead nucleotides, period.” In other words, it is not a COVID-19 infection.⁸

19. The chart below sets forth the manufacturer’s recommended cycle threshold for 6 commonly used PCR tests:

Manufacturer	Manufacturer’s Recommended Cycle Threshold
Xiamen Zeesan SARS-CoV-2 Test Kit (Real-time PCR)	45 cycles
Opti Sars CoV-2 RT-PCR Test	45 cycles ⁹
Quest SARS-CoV-2rRT-PCR Test	40 cycles ¹⁰
CDC 2019-Novel Coronavirus Real Time (RT-PCR)	40 cycles

⁷ See <https://www.who.int/news/item/20-01-2021-who-information-notice-for-ivd-users-2020-05> (last visited April 6, 2021).

⁸ See Podcast “COVID-19 with Dr. Anthony Fauci,” This Week in Virology (July 16, 2020).

⁹ See <https://www.fda.gov/media/137739/download> (last visited April 1, 2021).

¹⁰ See <https://www.fda.gov/media/136231/download> (last visited April 1, 2021).

Diagnostic Panel) Test	
Wren Labs COVID-19 PCR Test	38 cycles
LabCorp COVID-19 RT-PCR Test	35 cycles¹¹

20. The Food and Drug Administration (“FDA”) has merely authorized for emergency use, rather than approved, the use of PCR testing for SARS-Co-V-2 as a diagnostic aid in the setting of an acutely ill patient with suspected COVID-19, not in asymptomatic individuals. These tests remain experimental with no assurance of efficacy. Test manufacturers use disclaimers like this in their product manuals: “[t]he FDA has not determined that the test is safe or effective for the detection of SARS-Co-V-2.”¹²

21. The PCR test is also unsuitable as a tool for diagnosing the disease caused by the SARS-CoV-2 virus, COVID-19. The inventor of the PCR test, Kary Mullis, Ph.D., who won a Nobel Prize in chemistry for the invention in 1993, developed the test as a tool for use in laboratory research, but said that the test was never designed to diagnose disease. That is because, while COVID-19 PCR tests identify the presence of viral fragments of DNA, the tests do not provide accurate information about the presence of infectious, live virus as opposed to non-infectious (dead) viral fragments of SARS-CoV-2 or fragments of other viruses present in the sampled mucous.. The federal CDC apparently agrees. The July 2020 instruction manual for its 2019-Novel Coronavirus (2019-nCoV) Real Time RT-PCR Diagnostic Panel test includes these statements: “Detection of viral RNA may not indicate the presence of infectious virus or that 2019-nCoV is the causative agent for clinical symptoms”; and “This test cannot rule out diseases caused by other bacterial or viral pathogens.”¹³

¹¹ See <https://www.fda.gov/media/136151/download> (last visited April 1, 2021).

¹² See <https://www.optimedical.com/en/products-and-services/kits/opt-sars-cov-2-rt-pcr-test-kit/> (last visited April 2, 2021).

¹³ See <https://www.fda.gov/media/134922/download> accessed 11.6.2020 (last visited April 6, 2021).

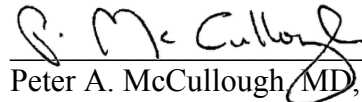
22. For all of the forgoing reasons, death certificates which report COVID-19 as a cause of death in reliance on PCR testing are intrinsically unreliable, especially where other co-morbidities are reported, autopsies are not performed, or the deceased was moribund prior to the time of purported infection with COVID-19.

23. I am available to testify in support of this Motion should the Court determine that it would like to hear further from me.

24. I DECLARE UNDER THE PENALTY OF PERJURY UNDER THE LAWS OF THE UNITED STATES OF AMERICA THAT THE FOREGOING INFORMATION CONTAINED IN THIS DECLARATION IS TRUE AND CORRECT.

April 8, 2021

Date



Peter A. McCullough MD, MPH

EXHIBIT A

Monday, February 1, 2021

CURRICULUM VITAE

PETER A. McCULLOUGH, MD, MPH, FACP, FACC, FCCP, FAHA, FNKF, FNLA, FCRSA

Business

Baylor University Medical Center
Worth Street Tower
3409 Worth St., #500
Dallas TX 75246
Desk: 214-841-2000
Cell: 248-444-6905
e-mail: PeterAMcCullough@gmail.com

Home

5231 Richard Avenue
Dallas, TX 75206

Birth date

December 29, 1962

Birthplace

Buffalo, NY, USA

EDUCATION

- 1) Certificate of Graduate Liberal Arts Studies: Southern Methodist University, December 17, 2016, principal faculty Dr. Anthony Picchioni, PhD, Adjunct Professor in Human Development, P.O. Box 750181, Dallas, TX 75275, 214-768-3417, www.smu.edu
 - Graduated with Honor
- 2) Master of Public Health: University of Michigan School of Public Health, August 19, 1994, Dean Noreen M. Clark, PhD, 109 Observatory Street, Ann Arbor, MI 48109-2029, phone 734-764-5454, www.sph.umich.edu
 - Major: General Epidemiology
- 3) Doctor of Medicine: University of Texas Southwestern Medical School, June 4, 1988, Dean Bryan M. Williams, MD, 5323 Harry Hines Boulevard, Dallas, TX 75235-9070, 214-648-3111, <http://www.utsouthwestern.edu/education/medical-school/>
 - Clinical year rank of 1 in 199, overall rank in class of 12 in 199
 - Alpha Omega Alpha Texas Gamma Chapter, installed March 17, 1988
- 4) Bachelor of Science: Baylor University, May 18, 1984, Chancellor Abner McCall, PhD, Office of the Registrar, Waco, TX 76798-7056, 254-710-1181, <http://www.baylor.edu/>
 - Double-major: Biology and Psychology
 - Graduated with Honor, degree rank of 29 in 131, university rank of 127 in 1,152

Peter A. McCullough, M.D., M.P.H.

- Alpha Lambda Delta Freshman Honorary, installed March 19, 1981

POSTGRADUATE TRAINING

- 1) Cardiovascular Diseases Fellowship: William Beaumont Hospital (WBH) (presently Oakland University William Beaumont School of Medicine), Division of Cardiology, 3601 W. Thirteen Mile Rd, Royal Oak, MI 48073, 248-551-4198, 7-1-94 to 6-30-97, Chief Cardiovascular Fellow for 1996-97, William W. O'Neill, MD, Program Director and Division Chief
- 2) Internal Medicine Residency: University of Washington School of Medicine, Department of Internal Medicine, 1959 NE Pacific, Seattle, WA 98195, (206) 543-3239, 3-year traditional track, 7-1-88 to 6-30-91, James F. Wallace, MD, Program Director, Paul G. Ramsey, MD, Chairman of Medicine

PROFESSIONAL EXPERIENCE

Baylor Scott and White Health, Baylor Health Care System, Baylor University Medical Center (BUMC), Baylor Heart and Vascular Institute, Baylor Jack and Jane Hamilton Heart and Vascular Hospital, Dallas TX, Texas A & M University Health Sciences Center, Department of Medicine, Division of Cardiology, Baylor Heart and Vascular Institute, 621 N. Hall St., #H030, Dallas, TX 75226, February 3, 2014 to present. Cardiovascular Governance Council, Kevin Wheelan, MD, Cardiology Division Chief and Chief Medical Officer, Heart Institute Office (214) 820-7500

Positions Held: 1) Professor in the Principal Faculty, Non-Tenure Track in the Department of Internal Medicine, Texas A & M University Health Sciences Center
 2) Chief of Cardiovascular Research
 3) Program Director, BUMC Cardiovascular Diseases Fellowship Program
 4) Vice Chief, BUMC Internal Medicine

St. John Providence Health System, Providence Park Heart Institute, Department of Medicine, Cardiology Section, 47601 Grand River Avenue, Suite B-125, Novi, MI 48374, September 1, 2010 to July 19, 2013. Department of Medicine Chair, Anibal Drelichman, MD: 248-849-3152, Cardiology Section Chief: Shukri David, MD, 248-465-5955

Positions Held: 1) Chief Academic and Scientific Officer (Academic Dean Equivalent), St. John Providence Health System, (2010 to 2013)
 2) Medical Director, Clinical Lipidology, Department of Medicine, Cardiology Section (2010 to 2013)

William Beaumont Hospital, Department of Internal Medicine, Divisions of Nutrition and Preventive Medicine, Department of Cardiology, 3601 West Thirteen Mile Road, Royal Oak, MI 48073, October 1, 2002 to 2010. Department of Medicine Chair: Michael A. Maddens, M.D., 248-551-0622, Department of Cardiology Chair: David E. Haines, M.D., 248-858-0404

Peter A. McCullough, M.D., M.P.H.

Oakland University William Beaumont School of Medicine, 472 O'Dowd Hall
2200 N. Squirrel, Rochester, MI 48309, Robert Folberg, MD, Medical School Dean, Kenneth
Hightower, PhD, Dean of Allied Health Sciences, 248-370-3562. Clinical Professor of Health
Sciences and Medicine (2007 to 2010)

Positions Held: 1) Consultant Cardiologist and Chief, Division of Nutrition and Preventive
Medicine (2002 to 2010), Department of Internal Medicine
2) Medical Director, Preventive Cardiology (2002 to 2010)
3) Medical Director, Lipid Apheresis Program (2007 to 2010)
4) Medical Director, Weight Control Center (2002-2005)

University of Missouri-Kansas City (UMKC) School of Medicine, Truman Medical Center,
Department of Medicine, Cardiology Section, 2301 Holmes St., Kansas City, MO 64108. August
18, 2000-September 30, 2002. Department of Medicine Chair: George R. Reisz, M.D, 816-556-
3450

Positions Held: 1) Associate Professor of Medicine (Tenure Track) and Cardiology Section
Chief

Henry Ford Health System (HFHS), Henry Ford Heart and Vascular Institute, 2799 W. Grand
Blvd., K-14, Detroit, MI 48202, July 1, 1997 to August 16, 2000. Cardiovascular Division Head:
W. Douglas Weaver, M.D, 800-653-6568

Positions Held: 1) Assistant Professor of Medicine (Tenure Track), Case Western Reserve
University School of Medicine, and HFHVI Senior Staff Cardiologist
Medical Director, Preventive Cardiology, 1999-2000
2) Program Director, Cardiovascular Diseases Fellowship Training Program,
1999-2000
3) Director of Cardiovascular Informatics Section, 1997-2000
4) Associate Director of the Center for Clinical Effectiveness, 1997-99
5) Associate Director of the Cardiovascular Diseases Fellowship Program,
1998-99

Emergency Physicians Medical Group, PC, 2000 Green Road, Suite 300, Ann Arbor, MI 48105,
800-466-3764. Emergency medicine attending at Mission Health McPherson Hospital, Howell,
1991-1997; Oakwood Beyer Hospital Center, Ypsilanti 1991-1997, and Mercy Hospital, Grayling
1991-1992

Positions Held: 1) Associate Member
2) Washtenaw County Human Services Deputy Medical Examiner, 1995-1996

Mercy Internal Medicine Associates, 308 Michigan Avenue, Grayling, MI 49738, Mercy
Hospital-Grayling, 1100 Michigan Avenue, Grayling, MI 49738, 517-348-5461. Internal
medicine attending at Mercy Hospital, Grayling, MI, 1991-1992

Peter A. McCullough, M.D., M.P.H.

Positions Held: 1) Coronary Care Unit Director
2) Physician Director of Cardiopulmonary Services

SPECIAL TRAINING

- 1) The Healthcare Forum Cardiovascular Health Fellowship, 1998-99
- 2) American Heart Association (AHA), 23rd 10-Day U.S. Seminar on the Epidemiology and Prevention of Cardiovascular Disease, July-August, 1997
- 3) University of Michigan Summer Session in Epidemiology, 1997-99
- 4) Stanford University Course on Medical Informatics, Palo Alto, CA, June, 1997
- 5) Current Practice of Vascular Ultrasound 3-Day Course, Chicago, IL, April, 1997
- 6) Advanced Pacemaker Concepts Course, CPI, Inc., Lansing, MI, 1995
- 7) Pacesetter Comprehensive Pacemaker 4-Day Course, Santa Fe, NM, 1997
- 8) Medtronic Bakken Education Tutorial and Medtronic Applied Physiological Research Laboratory Lead Implantation Training and Biventricular Implantation Training (2 sessions), Minneapolis, MN, 2001-2002
- 9) 2004 ASCeXAM Review Course, American Society of Echocardiography, San Francisco, CA, April 22-24, 2004
- 10) National Lipid Association Masters Course in Clinical Lipidology, Hilton Head, SC, August 21-23, 2008

CERTIFICATION AND LICENSURE

- 1) Licensed in the State of Washington 1988-1997 (#MD00027562), Michigan expires January 31, 2022 (#4301058147), and New York 1992 to present (#189283 inactive status), Missouri 2000-2002 (#2000165365 inactive status) and Texas expires May 31, 2022 (#P9222)
- 2) FLEX passed April 4, 1990, State of Washington, Department of Health, Board of Medical Examiners
- 3) Diplomate, American Board of Internal Medicine, Candidate #136084, September, 25, 1991, recertified May 1, 2001, valid through 2011, recertified June 10, 2011, valid through 2021, 510 Walnut Street, Suite 1700, Philadelphia, PA 19106-3699
- 4) Diplomate, American Board of Internal Medicine, Cardiovascular Diseases Subspecialty, Candidate #136084, November, 1997, valid through 2007, recertified October 1, 2007, valid through 2017, recertified September 28, 2017, valid through 2027, 510 Walnut Street, Suite 1700, Philadelphia, PA 19106-3699
- 5) Diplomate, American Board of Clinical Lipidology, September 27, 2008, 6816 Southpoint Parkway, Suite 1000, Jacksonville, FL 32216. Fellow, National Lipid Association
- 6) National Board of Echocardiography (NBE), Examination of Special Competence in Adult Echocardiography, 2004-2014 expired
- 7) Diplomate, American Board of Forensic Examiners, July 16, 1996, no expiration date

RECOGNITION

Peter A. McCullough, M.D., M.P.H.

Teaching:

1. Henry Ford Hospital, 1999 Chief Medical Resident's Best Teacher Award

Research:

1. Chest Foundation Young Investigator Award 2001, Philadelphia, PA, November 7, 2001, President's International Awards Ceremony
2. National Kidney Foundation (NKF) of Michigan, Innovations in Health Care Award Finalist 2008, East Lansing, MI, April 17, 2008
3. American College of Cardiology (ACC) Simon Dack Award for Scholarly Excellence by the Journal of the American College of Cardiology, March 5, 2009
4. 11th International Vicenza Award in Critical Care Nephrology, International Renal Research Institute, Vicenza, Italy, June 11, 2013

Postgraduate:

1. Founding Fellow, Cardiorenal Society of America, March 2016
2. Fellow, National Lipid Association, January, 2013
3. Fellow, National Kidney Foundation, January, 2012
4. Fellow, American College of Chest Physicians, February, 2001
5. Fellow, American College of Physicians, January, 2001
6. Fellow, American College of Cardiology, February, 1999

AFFILIATIONS

- 1) Alpha Omega Alpha, National Honor Medical Society, 1988 to present
- 2) American College of Emergency Physicians, Member, 1992-1994
- 3) American College of Forensic Examiners, Member 1996 to present
- 4) AHA, Council on Epidemiology and Prevention, 1995 to present
- 5) AHA, Grassroots Network, 1998-2000.
- 6) Central Society for Clinical Research, Member, 1999-2000
- 7) Council on Geriatric Cardiology, Member 1996-1997
- 8) Michigan Chapter of the ACC, Chair, Annual Cardiology Board Review, 1999-2000
- 9) Michigan State Medical Society, Member, 1997-2000, 2004 to 2009
- 10) The American Medical Informatics Association, 1997-2000
- 11) The Health Forum, Charter Cardiovascular Health Charter Alumni Representative, 1998 to 2002
- 12) Cardiorenal Society of America, Founding Executive Board Member, 2013 to present, Vice President 2014-2016, President 2016 to present
- 13) Dallas County Medical Society, 2014 to present
- 14) Texas Medical Association, 2014 to present
- 15) Baylor Alumni Association, 2015 to present
- 16) New York Academy of Sciences, 2016 to present

Peter A. McCullough, M.D., M.P.H.

EDITORIAL RESPONSIBILITIES

- 1) *Advances in Chronic Kidney Disease*, Editorial Board Member, 2003-present. [referenced through Elsevier Bibliographic Database, EMBASE/Excerpta Medica, MEDLINE]
- 2) *American Journal of Cardiology*, Associate Editor, 2014 to present
- 3) *American Journal of Kidney Disease*, [referenced through Elsevier Bibliographic Database, EMBASE/Excerpta Medica, MEDLINE] Associate Editor, 2006 to 2019, Guest Editor, 2011, 2012
- 4) *Arquivos Brasileiros de Cardiologia*, International Editorial Board, 2006 to present
- 5) *Biocritique*, Editorial Board, 2001 to 2013, www.biocritique.com
- 6) *Blood Purification*, Editorial Board 2018 to present
- 7) *Cardiovascular Clinician*, Editorial Board, 2011 to 2013, internet site, CARDIOVASCULARClinician.com[™]
- 8) *Cardiovascular Diagnosis and Therapy (CDT)*, Editorial Board (Print ISSN: 2223-3652; Online ISSN: 2223-3660, 2012 to present
- 9) *Cardiovascular Innovations and Applications (CVIA)*, Editorial Board 2015 to present
- 10) *Cardiorenal Medicine*, Associate Editor, 2016-2017, Editor-in-Chief 2018 to present
- 11) *Circulation*, Editorial Board, 2016 to present
- 12) *Circulation Heart Failure*, Editorial Board, 2008 to present, Associate Editor, 2008 to 2016, Guest Editor 2010, 2011, 2012
- 13) *Clinical Exercise Physiology*, Clinical Consultant to the Editorial Board, 1998-2002.
- 14) *Cochrane Renal Group Module*, 2008, Editorial Contributor, Centre for Kidney Research, The Children's Hospital at Westmead, Westmead NSW, Australia
- 15) *Expert Review of Cardiovascular Therapy*, Editorial Advisory Panel, 2002 to present, www.future-drugs.com
- 16) *Journal of the American College of Cardiology*, Editorial Consultant, 2003-present. "Elite Reviewer" Recognition, 2004, 2005, 2006, 2007, 2008, 2011, 2014, 2016 (DeMaria AN. The elite reviewer. J Am Coll Cardiol 2003;41(1):157-8.)
- 17) *Journal of Geriatric Cardiology*, Editorial Board Member, 2003-present. The Institute of Geriatric Cardiology, Chinese PLA Hospital, Beijing. [Joint China-U.S.A. publication]
- 18) *Journal of Biorepository Science for Applied Medicine*, Honorary Editorial Board, 2012 to 2018
- 19) *Journal of Clinical & Experimental Cardiology*, OMICS Publishing Group, Open Access, CrossRef, PubMed, DOAJ, Index Copernicus, Scientific Commons, EBSCO, 2010 to 2017
- 20) *Journal of Diabetes & Metabolism*, OMICS Publishing Group, Open Access, 2010 to 2017
- 21) *Journal of Interventional Cardiology*, "News and Views", Section Editor, 2000-2003. Editorial Board Member, 2003 to present
- 22) *Journal of Nephrology and Therapeutics*, Editorial Board, OMICS Publishing Group, Editorial Board, 2010 to 2017
- 23) *Reviews in Cardiovascular Medicine*, MedReviews, LLC, www.medreviews.com "Cardiorenal Function," Section Editor, 2001-2002, Associate Editor, 2003-2009, Co-Editor, 2009 to present

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- 24) *The American College of Cardiology Foundation ACCEL Audio Journal*, Editorial Board 2008 to present
- 25) *The Open Atherosclerosis & Thrombosis Journal*, [referenced through Bentham Open, PubMed, Google and Google Scholar] Editorial Board, 2008 to 2012
- 26) *The Open Heart Failure Journal*, [referenced through Bentham Open, PubMed, Google and Google Scholar] Editorial Board, 2008 to 2010
- 27) *Therapy*, [referenced through Elsevier Bibliographic Database, EMBASE/Excerpta Medica, MEDLINE], Editorial Board, 2008 to 2010

Manuscript Reviewer

- 1) *Advances in Chronic Kidney Disease*, 2004 to present (18)
- 2) *Advances in Medical Sciences*, 2012 to present (2)
- 3) *Advances in Therapy*, 2008 to present (1).
- 4) *American Family Physician*, 2004 to present (2)
- 5) *American Journal of Cardiovascular Drugs*, 2002 to present. (2)
- 6) *American Heart Journal (AHJ)*, 1998 to present (22)
- 7) *American Journal of Cardiology (AJC)*, 1999 to present (60)
- 8) *American Journal of Human Biology*, 2014 to present (1)
- 9) *American Journal of Hypertension*, 2011 to present (1)
- 10) *American Journal of Kidney Diseases (AJKD)*, 2002 to present (30)
- 11) *American Journal of Medicine (AJM)*, 1997 to present (7)
- 12) *American Journal of the Medical Sciences (AJMS)*, 2006 to present (3)
- 13) *American Journal of Nephrology*, 2004 to present (24)
- 14) *American Journal of Physiology: Renal Physiology*, 2006 to present (2)
- 15) *American Journal of Transplantation*, 2004 to present (1)
- 16) *Annals of Epidemiology*, 2004 to present (1)
- 17) *Annals of Internal Medicine*, 2008 to present (3)
- 18) *Annals of Noninvasive Electrocardiology*, 2009 to present (1)
- 19) *Antimicrobial Agents and Chemotherapy*, 2020 to present (1)
- 20) *Archives of Internal Medicine*, 2004 to present (2)
- 21) *Archives of Pathology and Laboratory Medicine*, 2007 to present (1)
- 22) *Arteriosclerosis, Thrombosis, and Vascular Biology*, 2010 to present (2)
- 23) *Autonomic Neuroscience: Basic and Clinical*, 2007 to present (1)
- 24) *BUMC Proceedings*, 2012 to present (3)
- 25) *Biochemia Medica*, 2012 to present (1)
- 26) *Biomed Central (BMC) Medical Imaging*, 2010 to present (1)
- 27) *Blood Purification*, 2010 to present (2)
- 28) *BMC Medicine*, 2007 to present (1)
- 29) *BMC Nephrology*, 2011 to present (1)
- 30) *BMJ Clinical Evidence*, 2008 to present (1)
- 31) *British Medical Journal (BMJ)*, 2009 to present (1)
- 32) *Canadian Medical Association Journal (CMAJ)*, 2006 to present (3)
- 33) *Cardiac Failure Review*, 2015 to present (1)

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- 34) *Cardiology*, 2007 to present (1)
- 35) *Cardiorenal Medicine*; 2013 to present (10)
- 36) *Cardiovascular Innovations and Applications*, 2016 to present (1)
- 37) *Cardiovascular Therapeutics*, 2010 to present (1)
- 38) *Catheterization and Cardiovascular Interventions*, 2000 to present (6)
- 39) *Chest*, 2000 to present (6)
- 40) *Circulation*, 1998 to present (100)
- 41) *Circulation Cardiovascular Interventions*, 2012 to present (1)
- 42) *Circulation Cardiovascular Quality and Outcomes*, 2010 to present (1)
- 43) *Circulation Heart Failure*, 2009 to present (4)
- 44) *Circulation Imaging*, 2012 to present (1)
- 45) *Cleveland Clinic Journal of Medicine*, 2008 to present (1)
- 46) *Clinica Chimica Acta*, 2013 (1)
- 47) *Clinical Cardiology*, 2001 (3)
- 48) *Clinical Chemistry and Laboratory Medicine*, 2010 to present (2)
- 49) *Clinical Exercise Physiology*, 2000-2002 (4)
- 50) *Clinical Journal of the American Society of Nephrology* 2008 to present (3)
- 51) *Clinical Kidney Journal*, 2012 to present (1)
- 52) *Clinical Medicine and Research*, 2008 to present (1)
- 53) *Clinical Nephrology*, 2008 to present (2)
- 54) *Clinical Physiology and Functional Imaging*, 2010 to present (1)
- 55) *Clinical Researcher*, 2002 to present (1)
- 56) *Clinics*, 2010 to present (1)
- 57) *Cochrane Collaboration*, 2009 to present (2)
- 58) *Congestive Heart Failure*, 2005 to present (4)
- 59) *Coronary Artery Disease*, 2005 to present (1)
- 60) *Critical Care Medicine*, 2008 to present (2)
- 61) *Current Medical Research and Opinion*, 2005 to present (1)
- 62) *Diabetes Care*, 2011 to present (2)
- 63) *Diabetes and Vascular Disease Research*, 2011 to present (1)
- 64) *Diabetes, Obesity, and Metabolism*, 2019 to present (1)
- 65) *Diabetic Medicine*, 2008 to present (1)
- 66) *Drug Benefit Trends*, 1999 (1)
- 67) *Drugs*, 2000 (2)
- 68) *European Heart Journal*, 1995 (12)
- 69) *European Journal of Cardiovascular Prevention and Rehabilitation*, 2006 (1)
- 70) *European Journal of Heart Failure*, 2012 (4)
- 71) *Expert Opinion on Pharmacotherapy*, 2003 to present (3)
- 72) *Expert Opinion Therapeutic Patents*, 2004 to present (1)
- 73) *Expert Review of Cardiovascular Therapy*, 2008 to present (2)
- 74) *Global Heart*, 2012 (1)
- 75) *Heart*, 2004 (2)
- 76) *Heart and Vessels*, 2007 (2)
- 77) *Hemodialysis International* 2013 (2)

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- 78) *Internal Medicine Journal (Australasia)*, 2009 to present (1)
- 79) *International Journal of Infectious Diseases* 2020 to present (2)
- 80) *International Journal of Nephrology*, 2010 to present (2)
- 81) *Journal of Biomarkers*, 2013 (1)
- 82) *Journal of Geriatric Cardiology*, 2017 (1)
- 83) *Journal of Internal Medicine*, 2009 to present (1)
- 84) *Journal of Interventional Cardiology (JIC)*, 1996 to present (9)
- 85) *Journal of the American College of Cardiology (JACC)*, 1998 to present (228)
- 86) *Journal of the American College of Cardiology: Heart Failure (JACC Heart Fail)*, 2014 to present (12)
- 87) *Journal of the American College of Cardiology: Imaging (JACC Imag)*, 2014 to present (6)
- 88) *Journal of the American College of Cardiology: Interventions (JACC Interv)*, 2010 to present (10)
- 89) *Journal of the American Medical Association (JAMA)*, 2002 to present (60)
- 90) *Journal of the American Medical Association Cardiology (JAMA Cardiology)*, 2016 to present (20)
- 91) *Journal of the American Society of Echocardiography (JASE)*, 2009 to present (1)
- 92) *Journal of the American Society of Nephrology (JASN)* 2005 to present (14)
- 93) *Journal of Cardiac Failure*, 2003 to present (10)
- 94) *Journal of Clinical Outcomes Management*, 2011 to present (1)
- 95) *Journal of Critical Care*, 2011, to present (1)
- 96) *Journal of General Internal Medicine*, 2008 to present (1)
- 97) *Journal of Human Hypertension*, 2010 to present (1)
- 98) *Journal of Inherited Metabolic Disease*, 2014 to present (2)
- 99) *Journal of Lipid Research*, 2010 to present (1)
- 100) *Journal of Managed Care*, 2004 to present (1)
- 101) *Journal of Physiology and Pathophysiology*, 2009 to present (1)
- 102) *Kidney and High Blood Pressure Research*, 2008 to present (1)
- 103) *Kidney International*, 2004 to present (8)
- 104) *Medical Science Monitor*, 2008 to present (1)
- 105) *Medicine & Science in Sports and Exercise*, 2005 to present (3)
- 106) *Nature Clinical Practice Cardiovascular Medicine*, 2004 to present (4)
- 107) *Nature Clinical Practice Nephrology*, 2008 to present (1)
- 108) *Nature Reviews Nephrology*, 2009 to present (3)
- 109) *Nephron*, 2005 to present (1)
- 110) *Nephrology*, 2009 to present (1)
- 111) *Nephrology, Dialysis, and Transplantation*, 2005 to present (7)
- 112) *New England Journal of Medicine*, 2006 to present (8)
- 113) *Pharmacological Research (Italy)*, 1999 (1)
- 114) *Pharmaceutical Sciences*, 2011 (1)
- 115) *PLoS Medicine*, 2005 (1)
- 116) *PLOS ONE*, 2013 (1)
- 117) *Prehospital Emergency Care*, 2015 (1)

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- 118) *Preventive Medicine*, 2008 (1)
- 119) *Rejuvenation Research*, 2007 (1)
- 120) *Renal Failure*, 2011 (2)
- 121) *The Lancet*, 1999 to present (11)
- 122) *The Lancet Diabetes*, 2013 to present (5)
- 123) *The Lancet Global Health*, 2015 to present (2)

Major Meeting Abstract Grader

- 1) ACC Scientific Sessions 2001 to present (10)
- 2) ACC I2 Summit, 2006 to present (2)
- 3) American Diabetes Association, 2008 to present (13)
- 4) AHA Scientific Sessions, 1997 to present (8)
- 5) American Medical Informatics Association, Annual Symposium, 1998-2001 (3)
- 6) International Academy of Cardiology World Congress on Heart Disease, Academy of Cardiology Annual Scientific Sessions—Mechanisms and Management, 2002-present (3)
- 7) Transcatheter Therapeutics (TCT), 2004 (1)

Grant Reviewer

- 1. National Medical Research Council, Singapore, 2003-2004
- 2. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Special Emphasis Panel/Initial Review Group 2006/01 ZDK1 GRB-9, 2005
- 3. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Special Emphasis Review Group, 1 R01 DK070033-01A2, 2006
- 4. National Institutes of Health, National Heart Lung and Blood Institute, Study Section, ZHL1 CSR-H (M1), March 6-7, 2006, Heart Failure Network
- 5. Diabetes UK, The British Diabetic Association, Macleod House, 10 Parkway, London NW1 7AA. December 24, 2008
- 6. National Institutes of Health National Institute of Diabetes and Digestive and Kidney Diseases, Special Review Panel, Chronic Renal Insufficiency Cohort Study (CRIC) and A Prospective Cohort Study of Kidney Disease in Children (CKiD) Study, February 23-25, 2012, March 6, 2013
- 7. National Institutes of Health National Institute of Diabetes and Digestive and Kidney Diseases, Special Review Panel, ZDK1 GRB-7 (O3)S in response to PAR-DK-09-247: Ancillary Studies to Major Ongoing Clinical Research Studies to Advance Areas of Scientific Interest within the Mission of the NIDDK (R01), July 11, 2012
- 8. Alberta Innovates Health Solutions Collaborative Research & Innovation Opportunities (CRIO) Grant Review, September, 2012
- 9. Health Research Board of Ireland, Health Research Awards, 2013
- 10. National Institutes of Health National Institute of Diabetes and Digestive and Kidney Diseases 2017/01 ZRG1 DKUS-R (55) Study Section 2016

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Guidelines Reviewer

1. Kidney Disease Improving Global Outcome (KDIGO) Guidelines Review
 - a. Prevention, Diagnosis, Evaluation and Treatment of Hepatitis C in Chronic Kidney Disease, Published April, 2008
 - b. Diagnosis, Evaluation, Prevention and Treatment of Chronic Kidney Disease related Mineral and Bone Disorders (CKD-MBD), Published August, 2009
 - c. Acute Kidney Injury (AKI), published March, 2012

CLINICAL TRIAL AND STUDY RESPONSIBILITIES

Overall Study Responsibilities: Steering and Executive Committees

- 1) Study Principal Investigator, Medicine vs Angiography for Thrombolytic Exclusion Patients (M.A.T.E.), 1994-1997, (multicenter, U.S., randomized controlled trial [RCT]). Status: closed.
- 2) Study Principal Investigator, The Resource Utilization Among Congestive Heart Failure Study (R.E.A.C.H.), 1998-2000, (single-center, prospective cohort study). Status: closed.
- 3) Study Principal Investigator, The Asthma, Beta-Agonists, and Congestive Heart Failure Study, (A.B.C.H.F.), 1998-1999, (single-center, case-control study). Status: closed.
- 4) Study Co-Principal Investigator, The Prevention of Radiocontrast Induced Nephropathy Clinical Evaluation (P.R.I.N.C.E.) Study, 1995-1998, (single-center, RCT). Status: closed.
- 5) Study Co-Principal Investigator, BNP Multinational Study, Principal Investigator, Alan Maisel, MD, Biosite Diagnostics, Inc., 2000-2006, (multicenter, international, prospective cohort study). Status: closed.
- 6) Study Co-Investigator, Prophylactic Oral Amiodarone Compared to Placebo for Prevention of Atrial Fibrillation Following Coronary Artery Bypass Graft Surgery (P.A.P.A.C.A.B.G.), 1996-1998, (single-center, RCT). Status: closed.
- 7) Study Co-Investigator, Rapid Early Bedside Markers of Myocardial Injury, 1998-1999, HFHS and Biosite Diagnostics, Inc. (prospective cohort study). Status: closed.
- 8) Member, Steering Committee, Clinical Study Protocol No. 2000-025: A Phase IIIb, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Determine the Safety, Efficacy, and Tolerability of Fenoldopam Mesylate in Subjects Undergoing Interventional Cardiology Procedures (CONTRAST), William W. O'Neill, MD and Gregg Stone, MD, Co-Principal Investigators, Abbott Laboratories, Inc., 2000-2003 (multicenter, US, RCT). Status: closed.

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- 9) Chair, National Steering Committee, Kidney Early Evaluation Program (KEEP) NKF, Member 2000-2005, Co-Chair 2005-2010, Chair 2010-present (multicenter, U.S., prospective cohort study). Annual budget ~\$1,325,198 (2009), ~\$1,233,832 (2010), ~\$1,614,953.00 (2011), ~\$989,500 (2012), ~\$1,217,000 (2013). Status: inactive.
- 10) Member, Steering Committee, Protocol No. 704.351 Evaluation of Synergy between Natrecor and Furosemide on Renal and Neurohormone Responses in Chronic Heart Failure: A Phase IV Study, Scios Inc., 2003-2005 (multicenter, U.S., randomized cross-over trial). Status: closed.
- 11) Member, Steering Committee, Protocol No. CCIB002FUS12. A Multicenter, Double-blind, Randomized, Parallel Group Study to Evaluate the Effects of Lotrel and Lotensin HCT on Microalbuminuria in Mild to Moderate Hypertensive Subjects with Type 2 Diabetes Mellitus, Novartis Pharmaceuticals, Inc., 2003-2006. Status: closed.
- 12) Rotating Executive Committee Principal Investigator Member, NIH HF-ACTION Trial (Exercise Training Program to Improve Clinical Outcomes in Individuals With Congestive Heart Failure), HL63747 01A2, 2006-2009. Principal Investigator, David Whellan, MD, status: closed.
- 13) Overall Study Principal Investigator, Neutrophil Gelatinase-Associated Lipocalin: A Novel Blood Marker for Risk of Developing Contrast Induced Nephropathy (ENCINO), multicenter, prospective, blinded cohort study, 2006-2009, status: closed.
- 14) Member, Steering Committee, VA NEPHRON-D: Diabetes iN Nephropathy Study, 2008 to 2013, trial stopped early for safety cardiovascular and acute kidney safety concerns in angiotensin converting enzyme inhibitor plus losartan arm, status: closed.
- 15) Member, External Expert Panel, National Institutes of Health, National Institute of Digestive and Diabetes and Kidney Diseases, Chronic Renal Insufficiency Cohort Study, status open, 2010 to present.
- 16) Member, Optimal Medical Management Subcommittee, National Institutes of Health, National Heart Lung and Blood Institute, International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA), status: open, 2011 to present.
- 17) Member, Steering Committee, National Institutes of Health, National Heart Lung and Blood Institute, International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA) in patients with Chronic Kidney Disease (ISCHEMIA-CKD), status: open, 2012 to present.

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- 18) Member, Steering Committee, Thrasos Innovation, Inc, A Phase II Multi-Center, Parallel-Group, Randomized, Double Blind, Proof-of-Concept, Adaptive Study Investigating the Safety and Efficacy of THR-184 Administered via Intravenous Infusion in Patients at Increased Risk of Developing Cardiac Surgery Associated-Acute Kidney Injury (CSA-AKI), status: closed, 2012 to 2015.
- 19) Overall Principal Investigator, AbbVie, Inc, Clinical Study Protocol M13-796, A Phase 2b, Randomized, Double-Blind, Placebo-Controlled, Safety and Efficacy Trial of Multiple Dosing Regimens of ABT-719 for the Prevention of Acute Kidney Injury in Subjects Undergoing High Risk Cardiac Surgery, status: closed, 2013 to 2014.
- 20) Overall Principal Investigator, Bioporto, Inc, The NGAL Test™ As An Aid in the risk assessment for AKI stage II and III in an Intensive Care Population, status: open 2017 to present.
- 21) Member, Global Expert Panel, Novo Nordisk, Inc, A Research Study to See How Semaglutide Works Compared to Placebo in People With Type 2 Diabetes and Chronic Kidney Disease (FLOW), status: open.

Overall Study Responsibilities: Endpoint Committees

- 1) Member, Critical Endpoints Committee, Treat Angina with Aggrastat and Determine Cost of Therapy with an Invasive or Conservative Strategy, TACTICS-TIMI 18 (Protocol 019-00), 1998-2000, (multicenter, international, RCT). Status: closed
- 2) Member, Study Endpoints Committee, A Phase II, Escalation Trial of Vasoflux™ in Patients Undergoing Thrombolysis with Streptokinase for Acute Myocardial Infarction, Protocol CLN-P-V18-07001, Parexel International Corporation, 1998, (multicenter, international, RCT). Status: closed
- 3) Member, Safety Endpoint Evaluation Committee, A Phase III, Single-Blind Controlled Study to Evaluate the Clinical Effects of a Hemoglobin-based Oxygen Carrier (HBOC-210) Given as a Transfusion Alternative in Patients Undergoing Orthopedic Surgery. (Protocol HEM-0115), Biopure Corporation with Quintiles, Inc., Clinical Event and Adjudication Services, 2000-2001. (multicenter, international, RCT). Status: closed
- 4) Member, Critical Endpoints Committee, Cerivastatin Heart Outcomes in Renal Disease: Understanding Survival (C.H.O.R.U.S.), Barry Brenner, MD and William F. Keane, MD, Co-Principal Investigators, Bayer Inc., 2000-2003 (multicenter, international, RCT). Status: study terminated early due to drug withdrawal from market
- 5) Member, Clinical Events Classification Committee, Correction of Hemoglobin and Outcomes in Renal Insufficiency (CHOIR), Ajay Singh, MD, Donal Reddan, MBBS, Principal Investigators, Ortho Biotech Inc., 2001-2004 (multicenter, international, RCT). Status: closed

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- 6) Member, Critical Endpoint Committee, A Randomised, Double-blind, Parallel Group, Phase 3, Efficacy and Safety Study of AZD6140 (Ticagrelor) Compared with Clopidogrel for Prevention of Vascular Events in Patients with Non-ST or ST Elevation Acute Coronary Syndromes (ACS) [PLATO – A Study of PLATelet inhibition and Patient Outcomes.], AstraZeneca, Inc., Duke Clinical Research Institute, 2008, status: closed
- 7) Chair, Clinical Endpoints Committee, Alere San Diego, Inc, Alere Prospective Blinded Study of a Novel Troponin Assay (PEARL), status: closed 2015
- 8) Chair, Adjudication Committee, Myeloperoxidase In the Diagnosis of Acute coronary Syndromes (MIDAS) study, Alere, Inc., status: closed 2012
- 9) Independent Endpoint Adjudicator, BioPorto Diagnostics, The NGAL test as an aid for the Diagnosis of AKI in an Intensive Care Population, Code of the Study: KLIN 12-005, status closed, 2015
- 10) Independent Endpoint Adjudicator, Ischemix, Inc., Safety and Efficacy of CMX-2043 for Protection of the Heart and Kidneys in Subjects Undergoing Coronary Angiography (CARIN), status: closed 2016
- 11) Chair, Data Adjudication Committee, Estimating versus Measuring Plasma Volume and Kidney Function in Acute Decompensated Congestive Heart Failure, Eudra-CT Number 2018-002638-18, Sponsor: Charite-Universitätsmedizin Berlin, FAST Biomedical, Inc, 2018-present

Overall Study Responsibilities: Data Safety Monitoring Committees

- 1) Member, External Advisory Committee/Data Safety Monitoring Board, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Polycystic Kidney Disease (PKD) Clinical Trials Network HALT-PKD Trial, Robert Schrier, MD, Principal Investigator, Committee Chair: William Henrich, MD, 2004-2008, Data Safety Monitoring Board, status: closed 2014
- 2) Chairman, Data Safety Monitoring Committee, Clinical Trials Program CS0011-A-U301, Daiichi Sankyo Pharma Development (DSPD) CS-011, Seven Core Trials of Rivoglitazone in Type 2 Diabetes: 1) A 26-week placebo-controlled trial of 1.0 and 1.5 mg rivoglitazone vs. 45 mg pioglitazone, as monotherapy in type 2 diabetics (CS0011-A-U301); 2) A 26-week placebo-controlled trial of 0.5, 1.0 and 1.5 mg rivoglitazone vs. 15, 30 and 45 mg pioglitazone, as monotherapy in type 2 diabetics (CS0011-A-U302); 3) A 26-week placebo-controlled trial of 1.0 and 1.5 mg rivoglitazone vs. 45 mg pioglitazone, in type 2 diabetics on metformin therapy, followed by a 26-week pioglitazone-controlled continuation period (CS0011-A-U303); 4) A 26-week placebo-controlled trial of 0.5 and 1.0 rivoglitazone vs. 30 mg pioglitazone, in type 2 diabetics on sulfonylureas therapy, followed by a 26-week pioglitazone-controlled continuation period (CS0011-A-U304); 5) A 26-week placebo-

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controlled trial of 0.5 and 1.0 mg rivoglitazone vs. 15 mg pioglitazone in type 2 diabetics on insulin therapy (CS0011-A-U305); 6) A long-term (12-24 months) randomized, general efficacy and safety study of rivoglitazone vs. pioglitazone, as monotherapy or add-on therapy, in type 2 diabetics (CS0011-A-U306); 7) A 26-week placebo-controlled trial of rivoglitazone and metformin, in type 2 diabetics (CS0011-A-U307), USFDA Special Protocol Assessment Agreement granted, status: closed, 2009 trials program terminated

- 3) Member, Data Safety Monitoring Committee, A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Cardiovascular Outcomes Following Treatment with Alogliptin in Addition to Standard of Care in Subjects with Type 2 Diabetes and Acute Coronary Syndrome SYR322_402, EXAMINE Trial Takeda Global Research and Development Center, Inc. (US) Takeda Global Research and Development Centre, Ltd. (Europe), status: 2009 trial stopped early for non-inferiority but futility on superiority outcome
- 4) Chair, Data Safety Monitoring Committee, Protocol D9120C00019, A randomised, double-blind, placebo controlled, multi-centre phase IIb dose finding study to assess the effect on GERD symptoms, safety and tolerability during four weeks treatment with AZD3355 in doses 60 mg, 120 mg, 180 mg and 240 mg bid as add-on treatment to a PPI in patients with GERD that are partial responders to PPI treatment, AstraZeneca, status: closed 2009, trials program terminated for safety
- 5) Member, Data Safety Monitoring Committee, Protocols: AMAG-FER-IDA-301, A Phase III, Randomized, Double-Blind, Placebo-Controlled Trial of Ferumoxytol for the Treatment of Iron Deficiency Anemia, Protocol: AMAG-FER-IDA-302, A Phase III, Randomized, Open-Label, Active Controlled Trial Comparing Ferumoxytol with Iron Sucrose for the Treatment of Iron Deficiency Anemia, Protocol: AMAG-FER-IDA-303, A Phase III, Open-Label Extension, Trial of the Safety and Efficacy of Ferumoxytol for the Episodic Treatment of Iron Deficiency Anemia, AMAG Pharmaceuticals, Inc., status: closed 2010, trial completed in 2013 without safety concerns
- 6) Chair, Independent Data Monitoring Committee, Protocol 402-C-0903 Bardoxolone Methyl Evaluation in Patients with Chronic Kidney Disease and Type 2 Diabetes: the Occurrence of Renal Events (BEACON), Reata Pharmaceuticals, Inc., status: trial stopped in 2012 early for cardiovascular and mortality safety concerns
- 7) Member, Independent Safety Council, Affymax Inc and Takeda Pharmaceutical Co., Omontys (peginesatide), status: closed, post-marketing surveillance led to voluntary drug withdrawal from market in 2013 for serious and fatal allergic reactions
- 8) Chair, Independent Data Monitoring Committee, AbbVie, Inc, Clinical Study Protocol M11-352 A Randomized, Multicountry, Multicenter, Double Blind, Parallel, Placebo-Controlled Study of the Effects of Atrasentan on Renal Outcomes in Subjects with Type 2 Diabetes and Nephropathy SONAR: Study Of Diabetic Nephropathy with Atrasentan, status closed 2018

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- 9) Chair, Independent Data Monitoring Committee, AbbVie, Inc., Clinical Study Protocol M13-958 A Phase 2b, Randomized, Double-Blind, Placebo-Controlled, Safety and Efficacy Trial of Multiple Dosing Regimens of ABT-719 for the Prevention of Acute Kidney Injury in Subjects Undergoing High Risk Major Surgery, status: closed 2015
- 10) Member, Data Monitoring Committee, Akebia Therapeutics, Inc., AKB-6548-CI-0007, Phase 2b Randomized, Double-Blind, Placebo-Controlled Study to Assess the Pharmacodynamic Response, Safety, and Tolerability to 20 Weeks of Oral Dosing of AKB-6548 in Subjects with Anemia Secondary to Chronic Kidney Disease (CKD), GFR Categories G3a-G5 (Stages 3, 4, and 5) (Pre-Dialysis), status: closed 2015
- 11) Member, Study Monitoring Team, Akebia Therapeutics, Inc., AKB-6548-CI-0011, Phase 2a Open-Label Study to Assess the Efficacy, Safety, and Tolerability of AKB-6548 in Subjects with Anemia Secondary to End Stage Renal Disease (ESRD), Undergoing Chronic Hemodialysis, status: closed 2016
- 12) Member, Data Monitoring Committee, Merck, Inc., Pfizer, Inc, Clinical Trials Program, Ertugliflozin (MK-8835/PF-04971729) Phase 2 and Phase 3 Development Program, status closed, 2012 to 2020
- 13) Member, Steering Committee, Medtronic, Inc., Monitoring in Dialysis, status: closed 2016
- 14) Member, Data Safety and Monitoring Board, St. Jude Medical, EnlighTN IV Multi-center, randomized, single-blind, sham controlled clinical investigation of renal denervation for uncontrolled hypertension, status: 2013 trial terminated before recruitment started
- 15) Chair, Data Safety Monitoring Board, Neumedicines, Inc., A Phase 2, Single-Dose, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of HemaMax™ (rHuL-12) in Healthy Subjects, status: closed 2016
- 16) Chair, Data Safety Monitoring Board, Reata Pharmaceuticals, Inc., A Phase 2 Study of the Safety, Efficacy, and Pharmacodynamics of RTA 408 in the Treatment of Friedreich's Ataxia, 2014 to 2019, status: closed
- 17) Chair, Data Safety Monitoring Board, Reata Pharmaceuticals, Inc., A Phase 2 Study of the Safety, Efficacy, and Pharmacodynamics of RTA 408 in the Treatment of Mitochondrial Myopathy, 2015 to 2019, status: closed
- 18) Member, Patient Safety Review Committee, Reata Pharmaceuticals, Inc., A dose-ranging study of the efficacy and safety of Bardoxolone Methyl in patients with pulmonary arterial hypertension (402-C-1302), 2014 to 2018, status: closed

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- 19) Chair, Data Safety Monitoring Board, Reata Pharmaceuticals, Inc., A Study of the Efficacy and Safety of Bardoxolone Methyl in Patients with Connective Tissue Disease-Associated Pulmonary Arterial Hypertension (CATALYST), 2016 to present, status: closed
- 20) Chair, Data Safety Monitoring Board, Reata Pharmaceuticals, Inc., A Phase 2/3 of Efficacy and Safety of Bardoxolone Methyl in Patients with Alport Syndrome (CARDINAL), 2017 to present, status: closed
- 21) Chair, Data Safety Monitoring Board, Sanfit, Inc., A double-blind, randomised, placebo-controlled study to assess the effect of SNF472 on progression of cardiovascular calcification on top of standard of care in end-stage-renal-disease (ESRD) patients on haemodialysis (HD) SNFCT2015-05, 2017 to 2019, status: closed
- 22) Chair, Data Monitoring Committee, Renew Research, KAI Research, A Randomized Pivotal Study of Renew™ NCP-5 for the Treatment of Mild Cognitive Impairment due to Alzheimer's Disease or Mild Dementia of the Alzheimer's Type, 2018 to present, status: closed
- 23) Chair, Data Safety Monitoring Committee, Sanofi, Inc, Multicenter, randomized, double-blind, placebo-controlled two stage study to characterize the efficacy, safety, tolerability and pharmacokinetics of GZ/SAR402671 in patients at risk of rapidly progressive Autosomal Dominant Polycystic Kidney Disease (ADPKD) STUDY NUMBER: EFC15392 STUDY NAME: SAVE-PKD COMPOUND: GZ/SAR402671, 2018 to present, status: open
- 24) Chair, Data Safety Monitoring Board, National Institutes of Health, National Heart, Lung and Blood Institute R34 NHLBI Clinical Trial Pilot Studies (R34) Reducing Arrhythmia in Dialysis by Adjusting the Rx Electrolytes/Ultrafiltration (RADAR), David Charytan, MD, PI, 2019 to present, status: open
- 25) Chair, Data Safety Monitoring Board, GZ402671 EFC15392 Multicenter, randomized, double-blind, placebo-controlled two stage study to characterize the efficacy, safety, tolerability and pharmacokinetics of GZ/SAR402671 in patients at risk of rapidly progressive Autosomal Dominant Polycystic Kidney Disease (ADPKD), Sanofi, status: open
- 26) Chair, Data Safety Monitoring Board, MEDI3506, Trials Portfolio, D9182C00001 A Phase 2 Randomized, Double-blinded, Placebo-controlled Study to Evaluate the Efficacy and Safety of MEDI3506 in Adult Subjects with Moderate-to-severe Atopic Dermatitis; D9181C00001 A Phase II, Randomised, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of MEDI3506 in Adult Participants with Uncontrolled Moderate-to-severe Asthma; D9180C00002 A Phase II, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy, Safety and Tolerability of MEDI3506 in Participants with Moderate to Severe Chronic Obstructive Pulmonary Disease and Chronic Bronchitis (FRONTIER 4); D9183C00001 A Phase 2b Randomized, Double-blind, Placebo-controlled, Study to Evaluate the Efficacy

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and Safety of MEDI3506 in Subjects with Diabetic Kidney Disease, Axio Inc, A Cytel Company, status: open

GRANT AWARDS

Original Research Grants

- G1) London JF (PI), Bis KG, Juni JE, Wilke N, DiCarli MF, Shetty AN, **McCullough PA**, Timmis GC. Magnetic Resonance vs. Positron Emission Tomography for the Detection of Myocardial Viability. Bracco Diagnostics Inc./SCA&I Grant, \$25,000 (WBH RC-453), 1997-98. Additional WBH Research Institute Mini-grant, \$5,000 (WBH Grant #RC-748). Level of involvement: author of the variable definitions, endpoints, and data analysis sections, 0% FTE. Status: closed 1998
- G2) **McCullough PA** (PI), Shah S, Noor H, Marks KR, McCabe KB, Zong L, McCord J, Khoury N, Ulcickas-Yood M, Ward RE. Diagnostic Accuracy of an Emergency Department Clinical Decision Unit in the Evaluation of Chest Pain. HFHS Small Projects Fund \$10,000 (HFHS Grant #A30785), 0% FTE. Status: closed 1997
- G3) Keteyian SJ (Co-PI), **McCullough PA** (Co-PI), Brawner CA, Rosman HS, Stein P, Weaver WD. A Prospective Study of Case Identification and Triage of Patients Eligible for Cardiac Rehabilitation. Merck & Co., U.S. Human Health, \$30,000 (HFHS Grant #E18037), 3% FTE. Status: closed 1998
- G4) **McCullough PA**. Novel Methods for Identifying High-Risk Patients for Subsequent Cardiovascular Events. Merck & Co., U.S. Human Health, \$20,000 (HFHS Grant #M1060), 0% FTE. Status: closed 1998
- G5) **McCullough PA**. Cardiovascular Informatics Development Award. Pfizer, Inc., \$10,000 (HFHS Grant #E60022), 0% FTE. Status: closed 1998
- G6) **McCullough PA**, Yee J, Soman S, Sallach J, Borzak S, Foreback C, Monaghan K, Tisdale JE, Bailey E, Bola P, Chase G, Marks KR, Weaver WD. A Prospective Dose-Ranging Trial of Folic Acid to Reduce Total Homocyst(e)ine Levels in Patients with End-Stage Renal Disease Undergoing Hemodialysis. HFHS Project Development Fund \$10,000 (HFHS Grant #A20003), 0% FTE. Status: closed 1999
- G7) **McCullough PA**. NuStep Recumbent Cross Trainer Product Development Pilot Study, NuStep, Inc., (single center, prospective pilot study), \$12,500.00, (WBH Grant #RC- 08-94847). Status: closed 2005
- G8) **McCullough PA**, Secondary Analyses from the PRINCE Trial, (single center data analysis), \$20,000, PLC Medical, Inc., (WBH #RC 08-94851) Status: closed 2005

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- G9) **McCullough PA**, Sullivan RA. A Systematic Review of Vascular Calcification in Patients with Chronic Kidney Disease and End-Stage Renal Disease, 2002-2003, Braintree Labs, Inc., \$40,000, 25% FTE (WBH Grant #RC 08-94833) Status: closed 2003
- G10) Pasas SA, Davies MI, **McCullough PA**. Determination of Protein-bound Homocysteine in Human Plasma using Capillary Electrophoresis with Electrochemical Detection in Patients with Chronic Kidney Disease, 2003-2004, AHA Predoctoral Fellowship Program (Pasas), \$38,000, 15% FTE (UMKC Grant #). Status: closed 2003
- G11) Collins AC, Gladstone E, Robitscher JW, **McCullough PA**, Klag M, Narva A, Gilberston D for the NKF. Demonstration project: state-based screening for chronic kidney disease. Response to CDC-RFA-DP06-004, demonstration project for identifying individuals at high-risk for CKD in the US. Centers for Disease Control, \$1,199,609, 12% FTE Status: closed 2007
- G12) **McCullough PA**, Principal Investigator. Neutrophil Gelatinase-Associated Lipocalin (NGAL): A Novel Blood Marker for Risk of Developing Contrast-Induced Nephropathy (ENCINO). Biosite/Inovise, Inc., \$229,000.00 (WBH #RC-94862), 0% FTE Status: closed 2009
- G13) Agrawal V, Barnes M, **McCullough PA**. Evaluation of CKD awareness in medical residents. WBH intramural mini-grant R/C# 98662, \$10,000.00, 0% FTE Status: closed 2008
- G14) **McCullough PA**, overall Principal Investigator transferred to Zalesin K. FDA Investigational New Drug Exemption (INDE) #060672. A Prospective, Randomized, Placebo-Controlled, Parallel-Group, Pilot Trial of Paricalcitol in the Treatment of Hyperparathyroidism in Patients after Roux-en-Y Gastric Bypass Surgery with Chronic Kidney Disease, Abbott Laboratories, Inc., \$496,600.00 (WBH #RC-90290), 0% FTE Status: closed 2009
- G15) **McCullough PA**, overall Principal Investigator transferred to Miller WM, FDA INDE #107750. Investigator Initiated Study. A Prospective, Double-Blind, Randomized, Parallel Group, Placebo-Controlled Trial of Aliskiren versus Placebo in Non-Diabetic, Normotensive Obese Patients with Microalbuminuria, Novartis, Inc., \$339,400.00 (WBH #RC-90345), Status: closed 2010
- G16) **McCullough PA**, overall Principal Investigator. Investigator Initiated Study, FDA Investigational New Drug (IND) #74707. A Phase 2, randomized, double-blind, placebo-controlled trial, to assess the efficacy and safety of deferiprone in the reduction of markers of contrast-induced acute oxidative kidney injury. Cormedix, Inc, \$857,745 (includes \$101,442 for Beaumont Research Coordinating Center). Study centers included Providence Hospital and Medical Center Southfield, St. John Hospital and Medical Center, Detroit, Northern Michigan Hospitals, Petoskey, MI, St. Vincent's Hospital, Indianapolis, IN, Fairfield Cardiac Cath Labs, LLC, Fairfield, OH, Oklahoma Heart Hospital, Oklahoma City, OK, Ohio

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Health Research Institute, Columbus, OH, Mercy St. Vincent Hospital, Toledo, OH, Status: closed 2011

- G17) **McCullough PA**, overall study Principal Investigator, A Prospective Randomized Parallel-Group Controlled Trial of Multiple Blood Biomarkers in the Personalized Management of Chronic Heart Failure, Baylor IRB 014-252, Baylor Foundation, 2014, \$78,639.20, status: closed 2016.
- G18) **McCullough PA**, overall study Principal Investigator, Baylor Hypertrophic Cardiomyopathy Program Development Project: Time-resolved, 3D phase contrast magnetic resonance imaging (MRI) (4D Flow) and Advanced Strain Rate Echocardiography in Patients with Hypertrophic Cardiomyopathy, Baylor IRB 014-175, Baylor Foundation, 2014, \$100,000.00, status: open
- G19) **McCullough PA**, overall study Principal Investigator, Preventive Cardiology Registry: Role of Proprotein Convertase Subtilisin/kexin type 9 (PCSK9) and Other Catabolic Determinants in Hypercholesterolemia in Patients with Suspected Heterozygous Familial Hypercholesterolemia Baylor IRB 014-122, Baylor Foundation, \$3,100.00, status: closed 2014
- G20) **McCullough PA**, overall study Principal Investigator and Study Chairman, Investigator Initiated Trial, "A Prospective, Double-blind, Placebo Controlled, Parallel Group, Randomized Trial of Extended Release Exenatide versus Placebo in Diabetic Patients with Type 4 Cardiorenal Syndrome: EXTEND-CRS", D5551L00004/ISSEXEN0013, FDA IND 123200, Baylor IRB 014-149, AstraZeneca, 2014, \$1,597,901.93, status: open
- G21) **McCullough PA**, overall study Principal Investigator, Iso-osmolar Contrast and the Timing of Coronary Angiography in the Multivariate Risk for Cardiac Surgery Associated with Acute Kidney Injury and Major Adverse Renal and Cardiac Events (MARCE), Baylor IRB 014-096, GE Healthcare, Inc, 2015, \$145,885.00, status open
- G22) **McCullough PA**, overall study Principal Investigator, Timing of coronary angiography and multivariate risk for cardiac surgery associated acute kidney injury and major adverse renal and cardiac events (MARCE), Baylor IRB 014-096, Baylor Foundation, \$8,100.00, status: closed 2016
- G23) Mendez J, **McCullough PA**, et al, co-investigator, Assessment of Multiple Blood Biomarkers in Patients with Advanced Heart Failure Undergoing Evaluation for Cardiac Transplantation and Mechanical Circulatory Support, Baylor IRB 014-300, Critical Diagnostics, Inc, \$10,400.00, status: closed 2016
- G24) Bottiglieri, T, **McCullough PA**, et al, co-investigator, Urinary 11dhTxB2 response to acetylsalicylic acid (aspirin) in cardiovascular disease progression and adverse outcomes, Baylor IRB 008-230, Corgenix, Inc., \$99,087.00, status: closed 2016

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- G25) Schussler JM, Vasudevan A, **McCullough PA**, co-investigator, Clinical outcomes and metabolomic and damage associated molecular patterns of acute kidney injury in patients undergoing percutaneous coronary intervention via the radial versus femoral artery approach, Baylor IRB 014-299, Baylor Health Care System Foundation, \$61,416.00, status: closed 2018
- G26) Tecson K, **McCullough PA**, coinvestigator, Contribution of Chronic Kidney Disease and Acute Kidney Injury to Heart Failure Outcomes, Baylor IRB 015-296, Baylor Health Care System Foundation, \$43,424.60, status: open
- G27) Vasudevan A, **McCullough PA**, coinvestigator, Burden of Cardiovascular Events Follow Percutaneous Coronary Intervention, Baylor IRB 015-297, Baylor Health Care System Foundation, \$40,000.00, status: closed 2018
- G28) Tecson, K, **McCullough PA**, Therapeutic Intensity of Lipid Lowering Therapy in Response to Recurrent Cardiovascular Events, Baylor IRB 017-106, Amgen, Inc., \$249,990.00 status: open
- G29) **McCullough PA**, Principal Investigator, A Case Finding Study of Familial Chylomicronemia, Akcea Pharmaceuticals, \$10,000.00, status: closed 2017
- G30) **McCullough PA**, Bottiglieri T, Tecson K. Baylor Foundation \$49,923.80. Identifying metabolomic profiles among genetically confirmed familial hypercholesterolemia, dyslipidemia without familial hypercholesterolemia, and healthy controls, status start-up 2019

Site Principal Investigator Contracts

- G1) Jafri S, **McCullough PA**, and the WATCH Investigators. Warfarin and Antiplatelet Therapy in Chronic Heart Failure, (W.A.T.C.H.) Field Center, Veterans Administration Cooperative Studies Program and Sanofi Pharmaceuticals, \$36,000.00 (HFHS Grant #B51008) status: closed 2000
- G2) Jafri S, **McCullough PA**, and the CHARM Investigators. Candesartan Cilexetil (Candesartan) in Heart Failure Assessment of Reduction in Mortality and Morbidity (C.H.A.R.M.) Field Center, 1999-2000, Astra Pharmaceuticals, \$56,000.00 (HFHS Grant #E09045) status: closed 2000
- G3) Schuger C, **McCullough PA**, and the MADIT Investigators. Multicenter Automatic Defibrillator Implantation Trial II (M.A.D.I.T.-II), Guidant Corporation/Cardiac Pacemakers (CPI), \$96,000 (HFHS Grant #G10087) status: closed 2000

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- G4) Schuger C, **McCullough PA**, and the MIRACLE Investigators. Multicenter InSync Randomized Clinical Evaluation (M.I.R.A.C.L.E.), Medtronic Inc., \$195,000, (HFHS Grant #G12006) status: closed 2000

- G5) **McCullough PA**, Shetty A, Soman S and the CHORUS Investigators. Cerivastatin Heart Outcomes in Renal Disease: Understanding Survival (C.H.O.R.U.S.), Barry Brenner, MD and William F. Keane, MD, Co-Principal Investigators, Bayer Inc., 2000-2003 (RCT), Clinical Site Contract, Bayer Pharmaceuticals, \$266,875.00 10% FTE (HFHS Grant #E05046) status: closed 2000

- G6) **McCullough PA**, Manley HJ and the CHORUS Investigators. Cerivastatin Heart Outcomes in Renal Disease: Understanding Survival (C.H.O.R.U.S.), Barry Brenner, MD and William F. Keane, MD, Co-Principal Investigators, Bayer Inc., 2000-2003 (RCT), Clinical Site Contract, Bayer Pharmaceuticals, \$279,000 10% FTE (UMKC Grant #E05046) status: closed 2001

- G7) Nowak R, McCord J, **McCullough PA** and the BNP Investigators. Breathing Not Properly Study (B.N.P. Multinational Study), Alan Maisel, MD, and Peter A. McCullough, MD, MPH, Co-Principal Investigators, Biosite Diagnostics, Inc., (prospective cohort study) Field Center Contract, Biosite Diagnostics, Inc., \$180,000.00 (HFHS Site), \$500,000.00, 0% FTE (HFHS Grant #E03005) status: closed 2001

- G8) Ehrman JK, **McCullough PA**. A Prospective Randomized Trial of a Personal Health Assistant in the Secondary Prevention of Heart Disease. Merck, Inc., \$220,961.00, 7% FTE (HFHS Grant #E41010) status: closed 2002

- G9) **McCullough PA** and the CORC Investigators. Kansas City Cardiomyopathy Questionnaire Interpretability Study, John A. Spertus, MD, MPH, Principal Investigator, Cardiovascular Outcomes Research Consortium (C.O.R.C.), 2001 (multicenter, U.S., prospective cohort study), \$21,400.00, status: closed 2002

- G10) **McCullough PA**, Rutherford BD, and the OAT Investigators. Occluded Artery Trial, Judith Hochman, MD, and Gervasio Lamas, MD, Co-Principal Investigators, National Institutes of Health, National Heart Lung and Blood Institute, \$54,000.00. 0% FTE (UMKC Grant #K531122) status: closed 2002

- G11) **McCullough PA** site Principal Investigator and National Executive Committee Member. Rapid Emergency Department Heart Failure Outpatient Trial, Biosite Diagnostics, \$21,000. 0% FTE (UMKC Grant #K531130) status: closed 2002

- G12) **McCullough PA** site Principal Investigator. African-American Heart Failure Trial (AHEFT). A Placebo-Controlled Trial of BiDil added to Standard Therapy in African American Patients with Heart Failure, NitroMed, Inc., \$20,000.00 (UMKC Proposal #9722, TMC Grant #261231) status: closed 2002

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- G13) **McCullough PA** and the IMAGING Investigators for Cardiology Clinical Studies, LLC. Investigation of Myocardial Gated SPECT Imaging as Initial Strategy in Heart Failure: The IMAGING in Heart Failure Trial, Dupont Pharmaceuticals Inc., \$20,000.00 (UMKC Proposal #9825, UMKC Grant #KG001278) status: closed 2002
- G14) **McCullough PA**, site Principal Investigator, and Ad Hoc Executive Committee Member. Heart Failure and a Controlled Trial Investigating Outcomes of Exercise Training. National Institutes of Health, National Heart, Lung, and Blood Institute, subcontracted through the Duke Clinical Research Institute, \$665,000, (NIH Grant #1 U01 HL63747 01A2, WBH Grant # RC 08-94837, Site #301) status: closed 2005
- G15) **McCullough PA**, site Principal Investigator, and Executive Committee Member. Protocol No. 704.351 Evaluation of Synergy between Natrekor and Furosemide on Renal and Neurohormone Responses in Chronic Heart Failure: A Phase IV Study, Scios Inc., 2003 (multicenter, U.S., randomized cross-over trial), \$105,447.50, (WBH Grant # RC 08-94836) status: closed 2005
- G16) **McCullough PA**, site Principal Investigator and National Co-Principal Investigator. Protocol No. CCIB002FUS12. A Multicenter, Double-blind, Randomized, Parallel Group Study to Evaluate the Effects of Lotrel and Lotensin HCT on Microalbuminuria in Mild to Moderate Hypertensive Subjects with Type 2 Diabetes Mellitus, Novartis Inc., (multicenter, U.S., randomized trial), \$63,649.90, (WBH Grant #RC 08-94838) status: closed 2006
- G17) **McCullough PA**, and the ACCOMPLISH Investigators. Protocol No. CCIB002.12301. Avoiding Cardiovascular Events through Combination Therapy in Patients Living with Systolic Hypertension, Novartis, Inc., 2003 (multicenter, multinational, randomized trial) \$159,241.00, (WBH Grant #RC 08-94844) status: closed 2006
- G18) **McCullough PA**, site Principal Investigator. Efficacy of Vasopressin Antagonism in Heart Failure: Outcome Study with Tolvaptan, Protocol #156-03-236, IND #50,533, Otsuka Maryland Research Institute, (multicenter, international, randomized trial), \$210,750.00, (WBH Grant #RC 08-94842 changed to #RC 08-94849) status: closed 2005
- G19) **McCullough PA**, site Principal Investigator. A Multicenter, Double-Blind, Randomized, Parallel Group, 6-week Study to Evaluate the Efficacy and Safety of Ezetimibe/Simvastatin Combination versus Atorvastatin in Patients with Hypercholesterolemia, Protocol #051/EZT544, Merck, Inc., (multicenter, U.S., randomized trial), \$18,840.00, (WBH Grant #RC 08-94843) status: closed 2006
- G20) **McCullough PA**, site Principal Investigator, A multicenter, double-blind randomized, parallel-group study to compare the effect of 24 weeks treatment with LAF237 (50 mg qd or bid) to placebo as add-on therapy in patients with type 2 diabetes inadequately controlled with metformin monotherapy. Novartis Pharmaceuticals, Inc., (multicenter, U.S., randomized trial), \$30,700.00, (WBH Grant #RC 08-94845) status: closed 2007

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- G21) **McCullough PA**, site Principal Investigator. A multicenter, double-blind randomized, parallel-group study to compare the effect of 24 weeks treatment with LAF237 (50 mg qd or bid) to placebo as add-on therapy to pioglitazone 45 mg qd in patients with type 2 diabetes inadequately controlled with thiazolidinediones monotherapy. Novartis Pharmaceuticals, Inc., (multicenter, U.S., phase III randomized trial) \$30,700.00, (WBH Grant #RC 08-94846) status: closed 2006
- G22) **McCullough PA**, site Principal Investigator. An 8-week, randomized, double-blind, parallel group, multicenter placebo and active controlled disease escalation study to evaluate the safety and efficacy of aliskiren in patients with hypertension, \$47,100.00 (WBH #RC 08- 94852) status: closed 2007
- G23) **McCullough PA**, site Principal Investigator. A randomized, double-blind study to compare the durability of glucose lowering and preservation of pancreatic beta-cell function of rosiglitazone monotherapy compared to metformin or glyburide/glibenclamide in patients with drug naïve, recently diagnosed type 2 diabetes, \$140,100.00, Novartis Pharmaceuticals (WBH #RC 08-94849) status: closed 2008
- G24) **McCullough PA**, site Principal Investigator. A multicenter, randomized, double-blind factorial study of the co-administration of MK-0431 and metformin in patients with type 2 diabetes who have inadequate glycemic control, \$36,735.00, Merck Research Laboratories (WBH #RC 08-94853) status: closed 2008
- G25) **McCullough PA**, site Principal Investigator. Multicenter, Randomized, Double-Blind Study to Evaluate the Efficacy & Safety of Ezetimibe/Simvastatin and Niacin Co-Administered in Patients with type IIa or Type IIb Hyperlipidemia, \$46,960.00, Merck Research Laboratories, MRK-091, (WBH #RC 08-94854) status: closed 2008
- G26) **McCullough PA**, site Principal Investigator. A Multi-Center, Randomized, Double-Blind, factorial Design study to evaluate the lipid-altering efficacy & safety of MK-0524B Combination Tablet in Patients with Primary Hypercholesterolemia or Mixed Hyperlipidemia \$40,849.00, Merck Research Laboratories, MRK-022. (WBH #RC 08-94855) status: closed 2007
- G27) **McCullough PA**, site investigator. An 8-week, multicenter, randomized, double-blind, parallel-group study to evaluate the efficacy and safety of the combination of valsartan/HCTZ/amlodipine compared to valsartan/HCTZ, valsartan/amlodipine, and HCTZ/amlodipine in patients with moderate to severe hypertension, \$43,500.00, Novartis Pharmaceuticals (WBH #RC 08-94857) status: closed 2007
- G28) **McCullough PA**, site Principal Investigator. A multicenter randomized, double-blind parallel arm, 6-week study to evaluate the efficacy and safety of ezetimibe/simvastatin versus atorvastatin in patients with metabolic syndrome and hypercholesterolemia at high

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risk for coronary heart disease, \$32,010.00. Merck Research Laboratories (WBH #RC 08-94861) status: closed 2008

- G29) **McCullough PA**, site Principal Investigator. A multicenter, randomized, double-blind study to evaluate the safety and efficacy of the initial therapy with coadministration of sitagliptin and pioglitazone in patients with type 2 diabetes mellitus, \$24,036.00, Merck Research Laboratories, MRK-064 (WBH #RC 08-94860) status: closed 2008
- G30) Dixon, SD, site PI, **McCullough PA**, Multinational Executive Committee. RENAL GUARD Pilot Trial. PLC Medical Systems, \$37,610.00 (WBH #RC- 90771) status: closed 2008
- G31) **McCullough, PA**, site Principal Investigator, A multi-center, randomized, double-blind, placebo and active controlled, parallel group, dose range study to evaluate the efficacy and safety of LCZ696 comparatively to valsartan, and to evaluate AHU377 to placebo after 8-week treatment in patients with essential hypertension. Novartis, Inc., \$31,965.28. (WBH #RC-94863) status: closed 2008
- G32) **McCullough PA**, site Principal Investigator. Paricalcitol capsules benefits in renal failure induced cardiac morbidity in subjects with chronic kidney disease stage 3b/4, (PRIMO Abbott Laboratories, ABT-M-10-030, \$157,992.00, (WBH #RC-94864) status: closed 2008
- G33) **McCullough PA**, site Principal Investigator. A randomized, double-blind, parallel group study to evaluate the effects of high-dose statin therapy on fluorodeoxyglucose (FDG) uptake in arteries of patients with atherosclerotic vascular disease. Merck Research Laboratories, MRK-081, \$86,994.00 (WBH #RC 08-90223) status: closed 2008
- G34) **McCullough PA**, site Principal Investigator. Patient registry for the Liposorber LA-15 system. Kaneka, Inc., \$7,515.00, (WBH #RC-90877) status: closed 2009
- G35) **McCullough PA**, site Principal Investigator. A 30-week multicenter, randomized, double-blind. Parallel-group study of the combination of ABT-335 and Rosuvastatin compared to rosuvastatin monotherapy in dyslipidemic subjects with stage 3 chronic kidney disease, Abbott M10-313, \$128,544.00, (WBH #RC-90212) status: closed 2009
- G36) **McCullough PA**, site Principal Investigator. A multicenter, randomized open label, active-comparator controlled study to assess the efficacy, safety, and tolerability of taspoglutide compared to exenatide in patients with type 2 diabetes mellitus inadequately controlled with metformin, thiazolidinedione, or a combination of both, Roche BC 21625, \$72,012.50, (WBC #RC-90245) status: closed 2010
- G37) **McCullough PA**, site Principal Investigator. A multicenter, randomized double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of taspoglutide compared to placebo in obese patients with type 2 diabetes mellitus inadequately

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controlled with metformin monotherapy, Roche BC 22092, \$38,387.50, (WBH #RC-90258) status: closed 2009

- G38) **McCullough PA**, site Principal Investigator. A safety and efficacy trial evaluating the use of apixaban for the extended treatment of deep vein thrombosis and pulmonary embolism, Bristol Myers Squibb-Pfizer CV185057, \$173,750.00, (WBH #RC-90288) status: closed 2009
- G39) **McCullough PA**, site Principal Investigator. A phase 3, active (warfarin) controlled, randomized, double-blind, parallel arm study to evaluate efficacy and safety of apixaban in preventing stroke and systemic embolism in subjects with nonvalvular atrial fibrillation, Bristol Myers Squibb-Pfizer CV1805030, \$173,750.00, (WBH #RC-90275) status: 2009
- G40) **McCullough PA**, site Principal Investigator. Treatment of Preserved Cardiac Function Heart Failure with an Aldosterone Antagonist Trial (TOPCAT), National Institutes of Health, National Heart, Lung, and Blood Institute, subcontracted through the New England Research Institutes, Inc., \$86,250.00, (WBH #RC-90267) status: closed 2010
- G41) **McCullough PA**, site Principal Investigator. An 8-week, randomized, double-blind, parallel group, multicenter, forced titration study to evaluate the efficacy and safety of aliskiren plus HCTZ versus aliskiren monotherapy in metabolic syndrome patients with stage 2 hypertension, Novartis, Inc., \$107,362.44 (WBH #RC-90277) status: closed 2009
- G42) **McCullough PA**, site Principal Investigator, Astute SAPPHIRE AST-111, Evaluation of Novel Biomarkers from Acutely Ill Patients at Risk for Acute Kidney Injury, Astute Medical, Inc, San Diego, CA, \$23,195.50 status: closed 2012
- G43) **McCullough PA**, site Principal Investigator, protocol number 156-10-292 titled "An Observational Prospective Registry to Identify Demographic and Clinical Characteristics of Patients Hospitalized with Euvolemic and Hypervolemic Hyponatremia and Assess the Comparative Effectiveness of Available Treatments and the Impact on Resource Utilization. Otsuka Inc., \$21,262.60 status: initial contract fulfilled, reopened under extension and registry completed in 2013
- G44) **McCullough PA**, site Principal Investigator, PROspective Multicenter Imaging Study for Evaluation of Chest Pain (PROMISE) Study, National Heart, Lung, and Blood Institute (NHLBI), Pamela Douglas, MD, Principal Investigator Clinical Coordinating Center, Duke Clinical Research Institute, \$17,000.00 status: closed 2012
- G45) **McCullough PA**, site Principal Investigator, ACZ885M/Canakinumab Clinical Trial Protocol CACZ885M2301 A randomized, double-blind, placebo-controlled, event-driven trial of quarterly subcutaneous canakinumab in the prevention of recurrent cardiovascular events among stable post-myocardial infarction patients with elevated hsCRP. Novartis, Inc., 2011 \$279,223.00 status: closed 2015

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- G46) **McCullough PA**, site Principal Investigator, AN-CVD2233 Evaluation of the Safety and Efficacy of Short-term A-002 (Varespladib) Treatment in Subjects with Acute Coronary Syndromes (VISTA-16) Anthera Pharmaceuticals, Inc., 2011 \$72,600.00 status: closed 2011
- G47) **McCullough PA**, site Principal Investigator, BC22140A Cardiovascular outcomes study to evaluate the potential of aleglitazar to reduce cardiovascular risk in patients with a recent acute coronary syndrome (ACS) event and type 2 diabetes mellitus (T2D), F. Hoffmann-La Roche Ltd, \$307,500.00 status: closed 2012
- G48) **McCullough PA**, site Principal Investigator, A Double-blind, Randomized, Placebo-controlled, Multicenter Study (Phase 2) to Evaluate the Safety and Efficacy of IV Infusion Treatment with Omecamtiv Mecarbil in Subjects with Left Ventricular Systolic Dysfunction Hospitalized for Acute Heart Failure (Protocol 20100754), Amgen, Inc, 253,464.00 status: closed 2012
- G49) **McCullough PA**, site Principal Investigator, MB102-073 A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Phase 3 Trial to Evaluate the Safety and Efficacy of Dapagliflozin in Subjects with Type 2 Diabetes with Inadequately Controlled Hypertension on an Angiotensin-Converting Enzyme Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB), Bristol-Myers Squibb Research and Development, 2011 \$34,115.00 status: closed 2012
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- G51) **McCullough PA**, site Principal Investigator, ABT M11350 RADAR: Reducing Residual Albuminuria in Subjects with Diabetes and Nephropathy with AtRasentan – A Phase 2b, Prospective, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate Safety and Efficacy, Abbott Laboratories, \$188,377.00 status: closed 2012
- G52) **McCullough PA**, site Principal Investigator, PEGASUS TIMI 54 trial, A Randomized, Double-Blind, Placebo Controlled, Parallel Group, Multinational Trial, to Assess the Prevention of Thrombotic Events with Ticagrelor Compared to Placebo on a Background of Acetyl Salicylic Acid (ASA) Therapy in Patients with History of Myocardial Infarction, AstraZeneca, 2011 \$98,530.00 status: transferred to PI Marcel Zughuib, MD
- G53) **McCullough PA**, site Principal Investigator, A Double-blind, Randomized, Placebo-controlled, Multicenter Study Assessing the Impact of Additional LDL-Cholesterol Reduction on Major Cardiovascular Events When AMG 145 is Used in Combination with Statin Therapy

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in Patients with Clinically Evident Cardiovascular Disease AMG 145 Amgen Protocol Number 20110118 EudraCT number 2012-001398-97, Amgen, Inc., \$1,732,062.80 status: closed 2016

- G54) **McCullough PA**, site Principal Investigator, A single-blind, multi-site trial of the dietary supplement anatabine (RCP006) to determine the effects on peripheral markers of inflammation in patients with elevated levels of C-reactive protein (CRP). Roskamp Institute Protocol Number RI-11-01, \$6700.00 status: closed 2012

- G55) **McCullough PA**, site Principal Investigator, Long-term safety and tolerability of REGN727/SAR236553 in high cardiovascular risk patients with hypercholesterolemia not adequately controlled with their lipid modifying therapy: a randomized, double-blind, placebo-controlled study LTS11717 Sanofi Aventis, \$252,000.00 status: closed 2013

- G56) **McCullough PA**, site Principal Investigator, Assessment of Clinical Effects of Cholesteryl Ester Transfer Protein Inhibition with Evacetrapib in Patients at a High Risk for Vascular Outcomes – the ACCELERATE Study, protocol I1V-MC-EIAN, Eli Lilly, \$421,202.00 status: closed 2014

- G57) **McCullough PA**, site Principal Investigator, AEGR-733-025, LOWER: Lomitapide Observational Worldwide Evaluation Registry, Aegerion, Inc., 2014, \$23,478.00 status: open

- G58) **McCullough PA**, site Principal Investigator, The Evaluation Of PF-04950615 (RN316), In Reducing the Occurrence of Major Cardiovascular Events in High Risk Subjects (SPIRE-1), Pfizer, Inc., \$145,343.90 status: closed 2016

- G59) **McCullough PA**, site Principal Investigator, The Evaluation Of PF-04950615 (RN316) In Reducing the Occurrence of Major Cardiovascular Events in High Risk Subjects (SPIRE-2), Pfizer, Inc., \$145,343.90 status: closed 2016

- G60) **McCullough PA**, site Principal Investigator, Long Term Observational Study in Patients with Homozygous Familial Hypercholesterolemia Treated with Kynamaro™, Genzyme-Sanofi, Inc., \$61,260.00 status: closed 2018

- G61) **McCullough PA**, site Principal Investigator, CUP14366, Alirocumab (SAR236553) Expanded Access Program for the Treatment of Severe Hypercholesterolemia Not Controlled with Maximal Tolerated Dose of Lipid Lowering Therapy Administered According to Standard of Care, Sanofi-Regeneron, Inc., 2015 \$8,500.00 status: closed 2015

- G62) **McCullough PA**, site Principal Investigator, Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-term Effectiveness (ADAPTABLE), Patient-Centered Outcomes Research Institute, 2015 \$29,400.00 status: open

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- G63) **McCullough PA**, site Principal Investigator, Assessment of Heart Failure using Condition-Specific Impact Assessments (PROMIS), Patient-Centered Outcomes Research Institute, 2015 \$81,840.00 status: 2017 status: closed
- G64) **McCullough PA**, site Principal Investigator, A Randomized Parallel-Group, Placebo-Controlled, Double-Blind, Event-Driven, Multi-Center Pivotal Phase III Clinical Outcome Trial of Efficacy and Safety of the Oral sGC Stimulator Vericiguat in Subjects With Heart Failure With Reduced Ejection Fraction (HFREF) - Vericiguat Global Study in Subjects With Heart Failure With Reduced Ejection Fraction (VICTORIA), Merck, Inc, 2017 \$878,163.90 status: closed
- G65) **McCullough PA**, site Principal Investigator, A phase III randomised, double-blind trial to evaluate efficacy and safety of once daily empagliflozin 10 mg compared to placebo, in patients with chronic Heart Failure with preserved Ejection Fraction (HFpEF), EMPEROR-PRESERVED, Boehringer-Ingelheim, 2017 \$170,099.00, status: open
- G66) **McCullough PA**, site Principal Investigator, A phase III randomised, double-blind trial to evaluate efficacy and safety of once daily empagliflozin 10 mg compared to placebo, in patients with chronic Heart Failure with preserved Ejection Fraction (HFpEF), EMPEROR-REDUCED, Boehringer-Ingelheim, 2017 \$170,099.00, status: open
- G67) Schiffmann R, **McCullough PA** Sub-Investigator, 014-097 PB-102-F03 (Sponsor - Protalix - PRX-102 1mg/kg q 2 weeks) A Multi Center Extension Study of PRX-102 Administered by Intravenous Infusions Every 2 Weeks for 60 Months to Adult Fabry Patients, status: open
- G68) Schiffmann R, **McCullough PA** Sub-Investigator, 014-288 AT1001-042 (Sponsor - Amicus - oral drug - chaperone) An Open-Label Extension Study to Evaluate the Long-Term Safety and Efficacy of Migalastat Hydrochloride Monotherapy in Subjects with Fabry Disease, status: closed.
- G69) Schiffmann R, **McCullough PA** Sub-Investigator, 016-153 PB-102-F20 (Sponsor - Protalix - BLINDED - ERT PRX-102 or Fabrazyme 1mg/kg q 2 weeks) A Randomized, Double blind, Active Control Study of the Safety and Efficacy of PRX-102 compared to Agalsidase Beta on Renal Function in Patients with Fabry Disease Previously Treated with Agalsidase Beta – Study Number PB-102-F20, status: open
- G70) Schiffmann R, **McCullough PA** Sub-Investigator, 017-189 PB-102-F50 (Sponsor - Protalix - PRX-102 infusion - 2mg/kg monthly) A Phase 3, Open Label, Switch Over Study to Assess the Safety, Efficacy and Pharmacokinetics of pengunigalsidase alfa (PRX-102) 2 mg/kg Administered by Intravenous Infusion Every 4 Weeks for 52 weeks in Patients with Fabry Disease Currently Treated with Enzyme Replacement Therapy: Fabrazyme® (agalsidase beta) or Replagal (agalsidase alfa), status: open

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- G71) Schiffmann R, **McCullough PA** 018-150 MODIFY (Sponsor - Idorsia - oral drug - substrate reduction) A multicenter, double-blind, randomized, placebo controlled, parallel-group study to determine the efficacy and safety of lucerastat oral monotherapy in adult subjects with Fabry disease, status: open

- G72) **McCullough PA**, site Principal Investigator, A Randomized, Double-blind, Placebo-controlled, Parallel-group Multicenter Study to Evaluate the Effects of Sotagliflozin on Clinical Outcomes in Hemodynamically Stable Patients with Type 2 Diabetes Post Worsening Heart Failure (SAR 439954), Sanofi US Services, Inc, \$214,600.00, 2019, status: open

- G73) **McCullough PA**, site Sub-Investigator, A Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Safety and Efficacy of Alirocumab in Patients with Homozygous Familial Hypercholesterolemia (R727-CL-1628), Regeneron Pharmaceuticals, Inc, \$143,503.00, 2019, status: closed

- G74) **McCullough PA**, site Sub-Investigator, A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Evinacumab in Patients with Homozygous Familial Hypercholesterolemia (R1500-CL-1629) Regeneron Pharmaceuticals, Inc, \$143,503.00, 2019, status: closed

- G75) **McCullough PA**, site Sub-Investigator, An Open-Label Study to Evaluate the Long-Term Efficacy and Safety of Evinacumab in Patients with Homozygous Familial Hypercholesterolemia (R1500-CL-1719) Regeneron Pharmaceuticals, Inc, \$65,317.44, 2019, status: open

- G76) Bottiglieri T, Tecson K, **McCullough PA**, Identifying metabolomic profiles among genetically confirmed familial hypercholesterolemia, dyslipidemia without familial hypercholesterolemia, and healthy controls, Baylor Health Care System Foundation, \$49,293.80, 2020 status: open

- G77) **McCullough PA**, Wheelan KE. BSWRI—Overall Principal Investigator, 001 A prospective clinical study of hydroxychloroquine in the prevention of SARS-COV-2 (COVID-19) infection in health care workers after high-risk exposures, FDA IND 149293, Baylor Health Care System Foundation, \$506,506.00, 2020 status: open

- G78) **McCullough PA**, Site Investigator, 4D-310-C001 entitled “An Open-label, Phase 1/2 Trial of Gene Therapy 4D-310 in Adult Males with Fabry Disease” 4D Molecular Therapeutics, Inc, \$101,210.85, 2020 status: open

- G79) **McCullough PA**, Site Investigator, TQJ230, Assessing the Impact of Lipoprotein (a) Lowering With TQJ230 on Major Cardiovascular Events in Patients With CVD (Lp(a)HORIZON) Novartis Pharmaceuticals Corporation, \$3,475,000.00, 2020 status open

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- A12) Sharma ND, Gandhi RS, Philbin EF, Weaver WD, **McCullough PA**. Which Patients with Left Ventricular Dysfunction Require Chronic Anticoagulation? A Prospective Analysis. *J Am Coll Cardiol* 1998;31:33A. [poster].
- A13) **McCullough PA**, Tobin KJ, Kahn JK, O'Neill WW, Thompson RJ. Prediction of In-hospital Survival after Sudden Cardiac Death: Derivation and Validation of a Clinical Model. *J Am Coll Cardiol* 1998;31:485A [poster].
- A14) Stevens M, **McCullough PA**, Tobin KJ, Speck JP, Westveer DC, Guido-Allen DA, Hartenburg DS, Puchrowicz-Ochocki SB, O'Neill WW. A Randomized Trial of Prevention Measures in Patients at High Risk for Contrast Nephropathy: Initial Results of the PRINCE Study. *J Am Coll Cardiol* 1998;31:469A [poster].
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- A18) Philbin EF, **McCullough PA**, Polanczyk CA, Jenkins PL, DiSalvo TG. Are Subjects in Heart Failure Trials Similar in Clinical Practice? *Circulation*, 1998;98:I-866 [moderated poster].
- A19) **McCullough PA**, Smith S, Borzak S. Understanding the Risks Associated with Baseline Renal Function in the Coronary Care Unit. *Circulation*, 1998;98:I-413 [poster].
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- A27) Hassan SA, Borzak S, Philbin EF, Soman S, Shah S, Weaver WD, Yee J, Marks KR, **McCullough PA**. The Impact Chronic Renal Insufficiency on Heart Failure Mortality after Hospitalization. *Journal of Cardiac Failure* 1999;5 Suppl 1:70. [poster].
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- T32) Rangaswami J, Lerma EV, **McCullough PA**, Editors. *Kidney Disease in the Cardiac Catheterization Laboratory*, 1st Edition 2020, ISBN-13: 978-3030454135 ISBN-10: 3030454134, Springer Nature Switzerland AG. Chapter 27 Ronco C, Ronco F, **McCullough PA.** A Call to Action to Develop Integrated Curricula in Cardiorenal Medicine, pp 449-463.
- T33) **McCullough PA**, Ronco C. *Textbook of Cardiorenal Medicine*, 1st Edition 2021, ISBN-13: 978-3030574598 ISBN-10: 3030574598, Springer Nature Switzerland AG. Chapter 1 **McCullough PA**, Kluger AY. Implications of Chronic Kidney Disease on the Epidemiology of Cardiovascular Disease, pp 1-6. Chapter 8 Rocha N, **McCullough PA.** Type 2 Cardiorenal Syndrome, pp 75-94. Chapter 17 **McCullough PA** Novel Biomarkers of Chronic Cardiorenal Disease, pp 227-234.

Invited Non-Peer Reviewed Works

- 1) **McCullough PA.** *Acute Renal Failure after Coronary Intervention*. American College of Cardiology Educational Highlights, Fall 1997 Issue, C.R. Conti, Editor
- 2) **McCullough PA**, Thompson RJ, Tobin KJ, Kahn JK, Schwender F, O'Neill WW. *Outcome of Out-of-Hospital Cardiac Arrest Survivors*. *Cardiology Review*, 2000;17:15-19

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- 3) Thompson RJ, **McCullough PA**, Kahn JK, O'Neill WW. *A Simple Scoring System to Predict Clinical Outcome after Resuscitation from Cardiac Arrest*. The Journal of Critical Illness, 1998;13:298-300
- 4) **McCullough PA**. *Clinical Evaluation. Part I. The Cardiopulmonary System*. Clinical Exercise Physiology, 1999;1:33-41
- 5) **McCullough PA**. *Clinical Evaluation. Part II. The Musculoskeletal and other Body Systems*. Clinical Exercise Physiology, 1999:1:92-99
- 6) **McCullough PA**. *Ridogrel: Literature Evaluation*. IDdb Reports, Current Drugs Ltd, February, 1999
- 7) **McCullough PA**. Debate Commentary: Complete Assessment of the Lipid Profile is Advised. Medical Crossfire, 1999;5:52
- 8) **McCullough PA**. Narrative Fields in Hospital Records. Invited comment on Loss of Narrative Data in New Zealand Health Statistics Public Hospital Injury Files, John Langley (Australasian Epidemiologist 1998:5.4). The Australasian Epidemiologist, 1999;6.1:17-18
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- 11) **McCullough PA**. Update from the International Society on Hypertension in Blacks. Rev Cardiovasc Med. 2002 Fall;3(4):192-95. PMID: 12650156
- 12) Nguyen PN, Spertus JA, **McCullough PA**. Is there a Heart Failure Epidemic? Cardiology Review 2002;19(9):32-36
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- 15) **McCullough PA**. The interface between heart disease and renal dysfunction: from association to action. ACC Current Journal Review 2003;12(2):20-24

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- 19) **McCullough PA**. The use of contrast media in peripheral, combined, and sequential procedures. Applications in Imaging: Cardiac Interventions: Contrast Use in Renally Compromised Patients 2003;Sept:47-51
- 20) **McCullough PA**. Chapter Four: Major Risk Factors for Chronic Kidney Disease. Kidney Early Evaluation Program Annual Data Report. Am J Kid Dis 2003;42(5):S34-S41
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- 23) **McCullough PA**, Franklin BA. Atherosclerosis: Conventional risk factors and cardiac events—debunking an old myth about prevalence. Rev Cardiovasc Med. 2004;5(3):185-186
- 24) Dutcher JR, **McCullough PA**. Commentary: Glycoprotein IIb/IIIa Inhibitors in Acute Coronary Syndromes. Evidenced Based Cardiovascular Medicine 2004;8:362-363
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- 28) **McCullough PA.** Clinical utility of blood natriuretic peptide levels. Business Briefing: US Cardiology 2006. Touch Briefings, Touch Cardiology. www.touchcardiology.com
- 29) **McCullough PA,** Wase A. Do implantable cardioverter-defibrillators improve survival in dialysis patients after cardiac arrest? Nature Clinical Practice Nephrology 2006; 2(2): 70-71
- 30) **McCullough PA.** Ranolazine: focusing on angina pectoris. Drugs of Today 2006, 42 (3):177-183
- 31) Singh PP, Nesto RW, Faxon DP, Lepor NE, Watson KE, Jacobs AK, **McCullough PA.** Best of the AHA Scientific Sessions 2006. Rev Cardiovasc Med. 2007 Winter;8(1):25-35. PMID: 17401300
- 32) **McCullough PA.** Safety Concerns Trump Public Health Benefit in the Eyes of the FDA Cardiorenal Panel. FDA Advisory Committee Did Not Recommend Approval Of Rimobant (ZIMULTI(R)) For Use In Obese And Overweight Patients With Associated Risks Factors. www.medicalnewstoday.com GLG NewsWatch for 6/14/2007
- 33) Friedewald VE, Goldfarb S, Laskey WK, **McCullough PA,** Roberts WC. The Editor's Roundtable: Contrast-Induced Nephropathy. Am J Cardiol. 2007 Aug 1;100(3):544-51. Epub 2007 Jun 4. PMID: 17659944
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- 35) **McCullough PA,** Chronic Kidney Disease as a Cardiovascular Risk State and Considerations for the Use of Statins. The Fats of Life, Lipoproteins and Vascular Disease Division, American Association of Clinical Chemistry, Volume XXII, No 1, 9-16 Winter 2008
- 36) Lepor NE, **McCullough PA,** Jacobs AK. Best of the AHA Scientific Sessions 2007. Rev Cardiovasc Med. 2008 Winter;9(1):62-9. PMID: 18418310
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- 38) Narala KR, LaLonde TA, Hassan S, **McCullough PA.** Management of Chronic Coronary Disease and Acute Coronary Syndromes in Patients with Chronic Kidney Disease. US Cardiology, 2011;8(2):123-31
- 39) Larsen T, Narala KR, **McCullough PA.** Type 4 Cardiorenal Syndrome: Myocardial Dysfunction, Fibrosis, and Heart Failure in Patients with Chronic Kidney Disease. J Clin Exp Cardiol 2012, 3:4. <http://dx.doi.org/10.4172/2155-9880.1000186>

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INVITED LECTURES: NATIONAL AND INTERNATIONAL FORUMS

- L1) "The Role of Triage Angiography in Acute Coronary Syndromes." Advances in Interventional Cardiology. WBH and the University of Maryland, Aruba, April, 1997.
- L2) "New Understandings of Anticoagulation During Unstable Angina." Co-Chair, American College of Cardiology 47th Annual Scientific Session, Atlanta, Georgia, March 30, 1998.
- L3) National Library of Medicine: The Emerging Health Information Infrastructure '99. "Electronic Outcomes", Washington, D.C., April 28, 1999.
- L4) Kansas City Southwest Clinical Society, 77th Annual Clinical Conference, Overland Park, Kansas: "Cardiac-Renal Risk: Incorporating Scientific Evidence into Your Practice," October 29, 1999.
- L5) The Health Forum, Best Practices, Chicago, Illinois. "Overview of Cardiovascular Health Fellowship," December 9, 1999.
- L6) AHA Scientific Conference on Existing Databases: Do They Hold Answers to Clinical Questions in Geriatric Cardiovascular Disease and Stroke? "Resource Utilization Among Congestive Heart Failure (R.E.A.C.H.) Database Overview," Washington, DC, January 27, 2000.
- L7) Health Forum Cardiovascular Health Fellowship Retreat: "Cardiovascular Risk and Health," Colorado Springs, CO, July 20, 2000.
- L8) Third Annual Center for Health Futures Advisory Board Meeting: "Congestive Heart Failure," La Jolla, CA, August 24, 2000.
- L9) Health Forum ACT Learning Collaborative Meeting: "Bridging Clinical, Community, and Population Health Strategies," St. Joseph, MO, September 20, 2000.
- L10) "Renal Disease as an Independent Risk Factor for Cardiovascular Disease in Diabetes," The Nexus of Cardiovascular and Renal Disease, Duke Clinical Research Institute, Tyson's Corner, VA, November 4, 2000.
- L11) "Atherosclerosis and Heart Disease," Winter Scientific Seminar, Missouri Society of the American College of Osteopathic Physicians, Kansas City, MO, January 27, 2001.
- L12) "Routine vs Selective Intervention in Acute Coronary Syndromes," Tenth Annual Cardiovascular Conference at Beaver Creek, Colorado, WBH and Duke University, February 14, 2001.

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- L13) “Intervention in the Patient with Renal Insufficiency,” Tenth Annual Cardiovascular Conference at Beaver Creek, Colorado, WBH and Duke University, February 16, 2001.
- L14) “The Epidemic of Cardiovascular Disease and Cardiorenal Risk,” The Nexus of Cardiovascular and Renal Disease, Duke Clinical Research Institute, Tyson’s Corner, VA, February 24, 2001.
- L15) “Cardiovascular Risk in Chronic Kidney Disease: Cardiorenal Risk,” Symposium on Cardio-renal Consequences of Angiotensin II, Insights from AII Blockade, NKF Spring Clinical Meeting, Orlando, FL, April 18, 2001.
- L16) Plenary Session: “Cardiac Emergencies and Cardiac Critical Care,” American College of Chest Physicians, CHEST 2001, Philadelphia, PA, November 5, 2001.
- L17) “Cardiorenal Risk,” The 33rd Annual ACC Cardiovascular Conference at Snowmass, Snowmass, Colorado, January 18, 2002.
- L18) “Epidemiology of Diabetes and Its Cardiovascular Risk” Eleventh Annual Cardiovascular Conference at Beaver Creek, Colorado, WBH and Duke University, February 14, 2002.
- L19) “Late-Breaking Clinical Trials II: A Prospective, Blinded Trial of B-Type Natriuretic Peptide as a Diagnostic Test for the Emergency Diagnosis of Heart Failure: The Breathing Not Properly (BNP) Multinational Study,” March 19, 2002, 51st Annual Scientific Session of the American College of Cardiology, Atlanta, GA.
- L20) “Scope of Cardiovascular Complications in Patients with Kidney Disease.” Plenary Session III: Reversing Cardiovascular Complications in Patients with Kidney Disease. International Society on Hypertension in Blacks: 17th International Interdisciplinary Conference on Hypertension and Related Risk Factors in Ethnic Populations, Miami, FL, June 11, 2002.
- L21) “Epidemiology: Renal—Chronic Kidney Disease.” Atherosclerotic Vascular Disease Conference, AHA, Boston, MA, July 8, 2002.
- L22) “B-type Natriuretic Peptide Should be a Part of the Diagnostic Evaluation of Heart Failure: Implications from the Breathing Not Properly (BNP) Multinational Study” International Academy of Cardiology 8th World Congress on Heart Failure—Mechanisms and Management, Washington, DC, July 15, 2002.
- L23) “Epidemiology and Physiology of Radiocontrast Nephropathy and its Impact on Outcomes” Prevent the Event Transcatheter Therapeutics 2002 Satellite Symposium, Washington, DC, September 26, 2002.

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- L24) “Calcification or ‘Phosphication’—Controversies of Calcium Phosphate Deposition: Invited Lecture: Coronary Calcification: A Predictor of Future Events or a Marker of Plaque Stability? American Society of Nephrology 2002 Annual Scientific Sessions Satellite Symposium, Philadelphia, PA, November 1, 2002.
- L25) “Renal Insufficiency and Clinical Outcome” Cardiovascular Seminar, AHA Scientific Sessions, Chicago, IL, November 18, 2002.
- L26) “Role of BNP in the Diagnosis of Heart Failure” ACC 34th Annual Cardiovascular Conference at Snowmass, CO, January 14, 2003.
- L27) “Managing the Patient with Combined Heart and Renal Failure—the Importance of Anemia” ACC 34th Annual Cardiovascular Conference at Snowmass, CO, January 14, 2003.
- L28) “The Emerging Healthcare Crisis of Obesity,” Twelfth Annual Cardiovascular Conference at Beaver Creek, CO, February 10, 2003.
- L29) “BNP in the Management of Heart Failure,” Twelfth Annual Cardiovascular Conference at Beaver Creek, CO, February 11, 2003.
- L30) “Contrast Nephropathy: Can it be Eliminated,” Twelfth Annual Cardiovascular Conference at Beaver Creek, CO, February 13, 2003.
- L31) “How Subtle Degrees of Renal Dysfunction Work as a Cardiac Risk Factor” First Cardiovascular Prevention Symposium: Updates and New Guidelines. AHA, Puerto Rico Chapter, San Juan, PR, March 22, 2003.
- L32) “What Is the Incremental Diagnostic Value of B-Type Natriuretic Peptide in Heart Failure?” Symposium. American College of Cardiology Scientific Sessions, 2003, Chicago, IL, April 1, 2003.
- L33) “Heart Failure Insights From Ejection Fraction” Session Co-Chair. Oral Contributions. American College of Cardiology Scientific Sessions, 2003, Chicago, IL, April 1, 2003.
- L34) “Chronic Renal Insufficiency as a Vascular Risk Factor” 14th Annual Scientific Sessions of the Society for Vascular Biology and Medicine, Chicago, IL, June 7, 2003.
- L35) “Phosphate Control and Calcification from a Cardiologist’s Perspective” World Congress of Nephrology Satellite Symposium, Berlin, Germany, June 12, 2003.
- L36) “Renal Disease is a Risk Factor for Cardiovascular Disease” ACC 29th Annual Tutorials in the Tetons 2003: Update in Cardiovascular Disease, August 25-27. 2003.

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- L37) “Diagnosis of Congestive Heart Failure: Is BNP Needed in Every Case?” ACC 29th Annual Tutorials in the Tetons 2003: Update in Cardiovascular Disease, August 25-27. 2003.
- L38) “How to Treat Combined Heart and Renal Failure with Hypertension” ACC 29th Annual Tutorials in the Tetons 2003: Update in Cardiovascular Disease, August 25-27. 2003.
- L39) “Which Agents Prevent Contrast-Induced Nephropathy?” European Society of Cardiology 2003 Symposium: Managing Patients at Risk for Contrast-Induced Nephropathy, Vienna, Austria, September 2, 2003.
- L40) “Epidemiology of Contrast Nephropathy” Symposium Chair for “A Contrast in Risk: Radiographic Imaging in the Renally Compromised Patient”, Satellite Symposium at the Transcatheter and Therapeutics Scientific Meeting, Washington, DC, September 17, 2003.
- L41) “Update on Cardiovascular Risk Reduction in Acute Coronary Syndrome Patients” 14th Annual Great Wall International Congress of Cardiology, Beijing, China, October 10-13, 2003.
- L42) “Renal Function and Dysfunction in Coronary Arteriography” 14th Annual Great Wall International Congress of Cardiology, Beijing, China, October 10-13, 2003.
- L43) “Interventional Cardiology 2003: Bench to Bedside and Beyond, Session III: Contrast Nephropathy: Separating the Hype from the Data. Antagonist: Contrast Nephropathy Can be Prevented.” AHA Scientific Sessions 2003, November 9, 2003, Orlando, FL.
- L44) “Reversing Diabetes and Its Consequences: Pipe Dream or Reality?” The 35th Annual Cardiovascular Conference at Snowmass, ACC, Snowmass, CO, January 12-16, 2004.
- L45) “Refining the Use of B-type Natriuretic Peptide as a Diagnostic Test in Clinical Practice” The 35th Annual Cardiovascular Conference at Snowmass, ACC, Snowmass, CO, January 12-16, 2004.
- L46) “Practical Management of Obesity for the Cardiologist: The Future of Dietary Management and Bariatric Surgery” The 35th Annual Cardiovascular Conference at Snowmass, ACC, Snowmass, CO, January 12-16, 2004.
- L47) “Update from the Hypertension World: JNC 7—What’s New and How Will it Influence Practice?” Thirteenth Annual Cardiovascular Conference at Beaver Creek, Colorado, WBH and Duke University, February 9-13, 2003
- L48) “The Lethal Couplet” Thirteenth Annual Cardiovascular Conference at Beaver Creek, Colorado, WBH and Duke University, February 9-13, 2003

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- L49) “BNP to Differentiate Between Cardiac and Extracardiac Sources of Dyspnea” 33rd Critical Care Congress, Society of Critical Care Medicine, Orlando, Florida, February 23, 2004.
- L50) “BNP Testing: Is It Ready for In-Hospital Monitoring of Therapy?” Point-of-Care Symposium, American College of Cardiology Scientific Sessions 2004, New Orleans, LA, March 8, 2004.
- L51) “Role of Brain Natriuretic Peptide Levels in Diagnosis” Natriuretic Peptides Symposium, American College of Cardiology Scientific Sessions 2004, New Orleans, LA, March 8, 2004.
- L52) “Renal Insufficiency and the Heart” Symposium Co-Chair, American College of Cardiology Scientific Sessions 2004, New Orleans, LA, March 9, 2004.
- L53) “Renal Insufficiency and Bypass Surgery” Renal Insufficiency and the Heart Symposium, American College of Cardiology Scientific Sessions 2004, New Orleans, LA, March 9, 2004.
- L54) “Causes and Consequences of Contrast-Induced Nephropathy and other Major Adverse Coronary Events” Contrast-Induced Nephropathy: Addressing the Needs of the High Risk Patient. A Satellite Symposium to the American College of Cardiology Scientific Sessions 2004, New Orleans, LA, March 9, 2004.
- L55) “Chronic Kidney Disease as a Cardiovascular Risk Factor” 2nd Annual Scientific Symposium, AHA of Puerto Rico, San Juan, PR, March 13, 2004
- L56) “Modern use of Angiotensin Receptor Blockade in Cardiovascular Disease” 2nd Annual Scientific Symposium, AHA of Puerto Rico, San Juan, PR, March 13, 2004
- L57) “Chronic Kidney Disease and Cardiovascular Disease” Satellite Symposium: Impact of Anemia Correction in Cardiovascular Patients, American Society of Hypertension Annual Scientific Session, New York, NY, May 22, 2004.
- L58) “Contrast-Induced Nephropathy—Clinical Anomaly or Reality” Satellite Symposium: Selecting Contrast Media - Implications for Patient outcomes, EuroPCR 2004, Paris, France, May 26, 2004.
- L59) “Contrast Nephropathy” Intervention 2004. American College of Cardiology Nationwide Symposium, CNN Center, Atlanta, GA, June 2, 2004.
- L60) “Technical Issues in Selection of the BNP Assay” Satellite Symposium of the American Association of Clinical Chemistry, Los Angeles, CA, July 28, 2004.

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- L61) “B-type Natriuretic Peptide in Clinical Practice” New Development in Cardiac Biomarkers for Detection and Management of Cardiovascular Diseases, EBAC Accredited Educational Programme, in conjunction with the European Society of Cardiology 2004 Annual Congress, Munich, Germany, August 30, 2004.

- L62) “Hot Topics: Renal Disease and Contrast Nephropathy—Implications for the PCI Patient” Session Moderator, Transcatheter Cardiovascular Therapeutics 2004, September 27, 2004.

- L63) “Definition and Pathophysiology of Contrast Nephropathy”, “Hot Topics: Renal Disease and Contrast Nephropathy—Implications for the PCI Patient” Transcatheter Cardiovascular Therapeutics 2004, September 27, 2004.

- L64) “Use of BNP in Clinical Practice” “Hot Topics: Clinical Utility of Biomarkers” Transcatheter Cardiovascular Therapeutics 2004, September 28, 2004.

- L65) “Contrast Media, Renal Insufficiency, and Radiocontrast Nephropathy” Introduction to Cardiac Catheterization and Indications for Percutaneous Interventions, 7th Annual Interventional Cardiology Self Assessment and Review Course, Transcatheter Cardiovascular Therapeutics 2004, September 29, 2004.

- L66) “Body Weight—Optimal Targets and How Good are We in Getting There” “Drug Combinations for Cardiovascular Disease” Duke Clinical Research Institute and U.S. Food and Drug Administration Think Tank, Washington, DC, October 8, 2004.

- L67) “Does Coronary Calcification Imply Plaque Instability?” Managing Cardiovascular and Calcium/Phosphorus Complications of CKD. Official Luncheon Symposium, Renal Week 2004, American Society of Nephrology, St. Louis, MO, October 20, 2004.

- L68) “B-type Natriuretic Peptide in the Diagnosis of Acute Heart Failure,” New Advances in the Diagnosis and Management of Acute Decompensated Heart Failure, Satellite Symposium to the AHA Scientific Sessions 2004, New Orleans, LA, November 8, 2004.

- L69) “Oportunidades para Aprimoramento no Tratamiento da Insuficiencia Cardiaca,” 3rd Congresso Brasileiro de Insuficiencia Cardiaca, II Simposio Luso-Brasileiro de Insuficiencia Cardiaca, I Encontro Multiprofissional em Insuficiencia Cardiaca, II Simposio Latinoamericano de Insuficiencia Cardiaca, (Portugese) Salvador, Bahia, Brasil, November 25-27, 2004.

- L70) “Peptideo Natriuretico Intravenoso-Perspectivas para Emprego na IC Descompensada,” 3rd Congresso Brasileiro de Insuficiencia Cardiaca, II Simposio Luso-Brasileiro de Insuficiencia Cardiaca, I Encontro Multiprofissional em Insuficiencia Cardiaca, II Simposio Latinoamericano de Insuficiencia Cardiaca, (Portugese) Salvador, Bahia, Brasil, November 25-27, 2004.

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- L71) “Nesiritide (Peptideo Natriuretico Intravenoso) uma Nova Arma no Tratamento da IC Grave e Decompensada,” 3rd Congresso Brasileiro de Insuficiencia Cardiaca, II Simposio Luso-Brasileiro de Insuficiencia Cardiaca, I Encontro Multiprofissional em Insuficiencia Cardiaca, II Simposio Latinoamericano de Insuficiencia Cardiaca, (Portuguese) Salvador, Bahia, Brasil, November 25-27, 2004.
- L72) “Conferencia Magna (Keynote Address): The Cardiorenal Intersection: Crossroads to the Future,” 3rd Congresso Brasileiro de Insuficiencia Cardiaca, II Simposio Luso-Brasileiro de Insuficiencia Cardiaca, I Encontro Multiprofissional em Insuficiencia Cardiaca, II Simposio Latinoamericano de Insuficiencia Cardiaca, (Portuguese) Salvador, Bahia, Brasil, November 25-27, 2004.
- L73) “Practical Use of BNP in the Diagnosis and Management of Heart Failure” Medical Grand Rounds, Olathe Regional Medical Center, Olathe, KS, December 3, 2004.
- L74) “Management of Heart and Renal Failure” The 36th Annual Cardiovascular Conference at Snowmass, ACC, Snowmass, CO, January 18, 2005.
- L75) “Contrast-Induced Nephropathy” The 36th Annual Cardiovascular Conference at Snowmass, ACC, Snowmass, CO, January 18, 2005.
- L76) “Combined Heart and Kidney Failure” Cardiovascular Conference at Snowmass, Aspen, CO, January 18, 2005.
- L77) “Practice Strategies and Protocols to Reduce Renal Complications” PCI: Understanding and Managing In-Hospital Cardiac and Renal Complications, 3rd European Summit, Chantilly, France, February 11, 2005.
- L78) “HDL Cholesterol: A Powerful New Therapeutic Target” 14th (Conference Chair) Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 14, 2005.
- L79) “BNP-ology, is the Enthusiasm Warranted?” (Conference Chair) 14th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 15, 2005.
- L80) “Anticoagulation for Atrial Fibrillation: Can Warfarin be Replaced?” (Conference Chair) 14th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 18, 2005.
- L81) “New Multimarker Strategies in the Diagnosis of Acute Coronary Syndromes” Satellite Symposium to the 54th Annual American College of Cardiology Scientific Sessions 2005, Orlando, FL, March 7, 2005.

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- L82) “Effect of Lowering LDL Level on Progression of Vascular Calcification” Reducing the Burden of Cardiovascular Calcification in Chronic Kidney Disease, Satellite Symposium to the Renal Physicians Association Annual Meeting, Washington, DC, March 20, 2005.
- L83) "Why Chronic Kidney disease is a CVD risk factor: Practical Implications in the Care of Cardiovascular Patients" Cardiology Grand Rounds, Clinical Science Institute, Galway, Ireland, UK, May 5, 2005.
- L84) “Clinical Application of B-type Natriuretic Peptide Levels in the Care of Cardiovascular Patients” EuroLab 2005, Glasgow, Scotland, UK, May 9, 2005.
- L85) “Anemia Is a Cardiovascular Risk Factor in Patients With Diabetic Nephropathy” The Kidney is a Key Link between Diabetes and Cardiovascular Disease: Managing Risk; Satellite Symposia to the Annual Scientific Sessions of the American Association of Clinical Endocrinology, Washington, DC, May 18, 2005.
- L86) “CIN: Emerging Trends in Identifying and Managing the At-risk Patient” Cardiovascular and Interventional Radiology Society of Europe (CIRSE) 2005, Nice, France, September 13, 2005.
- L87) “Recent Advances in Cardiac Markers and their Clinical Role in Cardiovascular Disease: Update of the BNP Consensus Panel Statements and Cost Effectiveness of BNP Testing” Turning Science into Caring Programme, Abbott European Laboratory Symposium, Wiesbaden-Delkenheim, Germany, October 14, 2005.
- L88) “Epidemiology and Prevention of Contrast Nephropathy” Transcatheter Therapeutics Annual Scientific Sessions, Washington, DC, October 19, 2005.
- L89) “BNP—What Does it All Mean?” Heart Failure 2005: What to Do for the Failing Left Ventricle” AHA Symposium in Conjunction with the 2005 Scientific Sessions, Dallas, TX, November 11, 2005.
- L90) “How to Use Cardiac Biomarkers in Heart Failure” 2005 Annual Scientific Sessions of the AHA, Dallas, TX, November 14, 2005, broadcasted nationally as “Best of Sessions 2005 on Wednesday, November 30 from 1:00-2:30PM EST”
- L91) “Chronic Kidney Disease as a Cardiovascular Risk State: Practical Management for the Cardiologist” St. Vincent’s Hospital, University of British Columbia, Distinguished Speakers in Cardiovascular Medicine, 2005-2006, Vancouver, BC, Canada, December 1, 2005.
- L92) “Anemia, Chronic Kidney Disease, and Cardiovascular Disease: Diagnosis, Prognosis, and Treatment. Nephrology Grand Rounds, University of British Columbia, St. Vincent’s Hospital, Vancouver, BC, Canada, December 2, 2005.

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- L93) “The Deadly Triangle of Anemia, Kidney and Heart Disease: Implications for Treatment and Management” 37th Annual Cardiovascular Conference at Snowmass, January 20, 2006, Snowmass, CO.
- L94) “Anemia in Cardiovascular Patients: Diagnosis, Prognosis, and Therapy.” AHA, Prevention VIII Conference: Kidney Disease, Hypertension, and Cardiovascular Disease, January 27, 2006, Orlando, FL.
- L95) “Update on Bariatric Surgery” (Conference Chair) 15th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 17, 2006.
- L96) “Multimarker Approach to Chest Pain.” Satellite Symposium to the Annual Scientific Sessions of the American College of Cardiology, March 11, 2006, Atlanta, GA.
- L97) “Preventing Contrast Nephropathy: What Works?” American College of Cardiology Annual Scientific Sessions (ACC.06 and the i2 Summit 2006), March 14, 2006, Atlanta, GA.
- L98) “Consensus statements on strategies to reduce the risk of CIN.” Satellite Symposium Society for Cardiac Angiography and Intervention 29th Annual Scientific Sessions (Symposium Chair): Consensus Statements on Contrast-Induced Nephropathy (CIN): Report of an International, Multidisciplinary Panel, Chicago, IL, May 11, 2006.
- L99) “Contrast-induced nephropathy: identifying and managing the patient at risk.” Euro PCR 2006 Satellite Symposium: The Underestimated Impact of Contrast Media on Patient Outcomes in PCI (Symposium Chair), Paris, France, May 27, 2006.
- L100) “Debate: Acute Decompensated Heart Failure--Biomarker will suffice” 17th Annual Scientific Sessions of the American Society of Echocardiography, Baltimore, MD, June 6, 2006.
- L101) “Heart and Kidney: Clinical Impact of Contrast Media” Update on Cardiovascular Disease 2006, Casa Di Cura Montevergine, Napoli Castel Dell’Ovo, Naples, Italy, June 19, 2006.
- L102) “Cardiovascular Disease in CKD: Where Does Calcium Fit In?” Satellite Symposia: Current Strategies for the Management of Hyperphosphatemia in End-Stage Renal Disease. European Renal Association/European Dialysis and Transplantation Association Annual Scientific Meeting, Glasgow, Scotland, July 17, 2006.
- L103) “Applications of BNP in Cardiovascular Disease” Satellite Symposia: New and Evolving Markers for Cardiovascular Disease: Myeloperoxidase (MPO) and BNP. American Association of Clinical Chemistry Annual Meeting, Chicago, IL, July 26, 2006.

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- L104) “Clinical Applications of B-type Natriuretic Peptide Testing” Clinical Biochemistry Satellite Symposium: The Role of Biochemical Markers in Clinical Cardiology, Sponsored by the Australasian Association of Clinical Biochemists at the 54th Annual Scientific Meeting of the Cardiac Society of Australia and New Zealand, Canberra, Australia, August 4, 2006.
- L105) “Update on BNP in the Management of Heart Failure” 54th Annual Scientific Meeting of the Cardiac Society of Australia and New Zealand, Canberra, Australia, August 6, 2006.
- L106) “Update on BNP in the Management of Heart Failure” Cardiology Grand Rounds, Royal North Shore Hospital, Sydney, Australia, August 7, 2006.
- L107) “Contrast-Induced Nephropathy: Identifying and Managing the Patient at Risk” Advances in Contrast-Enhanced Imaging: Improving Outcomes and Reducing Risks of Iodinated Contrast (Chairman), a CME Satellite Symposium at the Transcatheter Therapeutics 2006 Conference, Washington, DC, October 24, 2006.
- L108) “Cardiorenal Syndrome: Etiology, Therapy, and Prognosis” Unresolved Issues in Heart Failure, Cardiovascular Seminars, 2006 Annual Scientific Sessions of the AHA, Chicago, IL, November 14, 2006
- L109) “Prevention and Management of CAD in CKD” Coronary Artery Disease in CKD: Updating the Pathophysiology and Management. Official Symposium of the American Society of Nephrology, Sand Diego, CA, November 16, 2006.
- L110) “Pharmacologic Prevention of Sudden Death in Dialysis Patients” Sudden Death in Hemodialysis Patients: Towards Prevention. American Society of Nephrology Renal Week 2007, San Diego, CA, November 17, 2006.
- L111) “Contrast Nephropathy: Finding Consensus on a Rational Approach” Radiology Grand Rounds, Hôpital Notre-Dame, University of Montreal, Canada, November 23, 2006.
- L112) “Contrast Nephropathy: Finding Consensus on a Rational Approach” Radiology Grand Rounds, Hôpital St-Luc, University of Montreal, Canada, November 23, 2006.
- L113) “Cardiorenal Syndrome and Anemia” 3rd Annual Heart Failure University (HFU) Cardiovascular Fellows Program, Los Angeles, CA, December 2, 2006.
- L114) “Implications of Age-Related Decline in Renal Function” 16th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 12, 2007.
- L115) “Using BNP in Your Practice: Pearls and Pitfalls” 16th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 15, 2007.

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- L116) "Consensus Panel Findings on Contrast Nephropathy" 16th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 16, 2007.
- L117) "Measuring BNP in ACS," American College of Cardiology Scientific Sessions Satellite Symposium, "ACS & Biomarkers: From Molecules to Patient Management", New Orleans, LA, March 24, 2007.
- L118) "Anemia Correction and CVD Trials" "Ask the Experts" clinicaltrialresults.org, American College of Cardiology Scientific Sessions, New Orleans, LA, March 26, 2007.
- L119) "CKD and CVD: Interaction and Risk Factors", Kidney Disease: The Unrecognized Silent Killer, NKF 2007 Scientific Meetings, Orlando, FL, April 11, 2007.
- L120) "Contrast-Induced Nephropathy: A Meta-Analyses of the Renal Safety of Iodixanol" Special Lecture for the Radiological Society of the Republic of China, National Yang-Ming University, School of Medicine, Taipei, Taiwan, May 4, 2007.
- L121) "Contrast-Induced Nephropathy: A Meta-Analyses of the Renal Safety of Iodixanol" Annual Meeting of Kaohsiung Society of Radiology, Chang Gung Memorial Hospital, Kaohsiung Hsien, Taiwan, May 5, 2007.
- L122) "Meta-Analyses of the Renal Safety of Iodixanol", Plenary Session, 15th Annual Scientific Congress of the Hong Kong College of Cardiology, Hong Kong, SAR, May 6, 2007.
- L123) "Contrast-Induced Nephropathy: A Meta-Analyses of the Renal Safety of Iodixanol" Cardiology Special Lecture, 12th Department of Cardiology, Beijing AnZhen Hospital, Beijing, Peoples Republic of China, May 7, 2007.
- L124) "Prevention of CIN during PCI in Diabetic Patients: Proposal of a Guideline" (Prevencion del Fracaso Renal Inducido por Contraste en Pacientes Diabeticos Sometidos a Intervencionismo Coronario: Propestuesta de un Protocolo Actuacion), Optimizacion del Tratamiento de Revascularizacion Percutanea en Pacientes Diabeticos, TEAM (Terapia Endovascular & Miocardica), Hospital del Mar, Barcelona, Spain, May 11, 2007.
- L125) "Acute Kidney Injury from Iodinated Contrast: Findings from an International Panel," Hungarian Society of Cardiology Annual Scientific Meeting (Magyar Kardiologusok Tarsasaga Tudomanyos Kongresszusa) Balatonfured, Hungary, May 12, 2007.
- L126) "Which Types and Which Amount of Physical Activities to Achieve and Maintain a Healthy Body Weight?" 4th Metabolic Syndrome, Type II Diabetes, and Atherosclerosis Congress (MSDA), 2007, Lisbon, Portugal, May 19, 2007.

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- L127) “The Role of BNP in Patients with Shortness of Breath,” Laboratory Diagnostic Technologies for Patients with Shortness of Breath, Satellite Symposium to the American Association of Clinical Chemistry Annual Scientific Meeting, San Diego, CA, July 18, 2007.
- L128) “Acute Kidney Injury after Contrast: A Serious Problem by Any Name”, Hemodynamics, Electrolytes, Acute Kidney Injury: Novel Considerations in Contrast Selection, Transcatheter Cardiovascular Therapeutics 2007 Annual Meeting Satellite Symposium, Washington, DC, October 23, 2007.
- L129) “Vascular Calcification: Myth versus Reality: A Cardiologist's Perspective,” Changing Paradigms: Evolving Bone and Mineral Metabolism Treatment in CKD, An American Society of Nephrology 2007 Official Symposia, San Francisco, CA, November 3, 2007.
- L130) “Contrast-Induced Nephropathy” Cardiology Grand Rounds, Auckland City Hospital, Auckland, New Zealand, November 22, 2007.
- L131) “Practical Use of Natriuretic Peptides in Cardiovascular Disease” North Shore Hospital- Waitemata Health, Takapuna, Auckland, New Zealand, November 22, 2007.
- L132) “Practical Use of Natriuretic Peptides in Cardiovascular Disease” Waikato Hospital, Hamilton, New Zealand, November 23, 2007.
- L133) “Practical Use of Natriuretic Peptides in Cardiovascular Disease” Wakefield Hospital, Adelaide, Australia, November 23, 2007.
- L134) “Clinical Utilization of Cardiac Troponin and Natriuretic Peptides in ACS and CHF” Satellite Symposium to Australasian Emergency Meeting (ACEM), Gold Coast, Brisbane, Australia, November 27, 2007.
- L135) “Clinical Utilisation of Cardiac Troponin and Natriuretic Peptides in ACS and CHF: Part 1: Congestive Heart Failure, Part 2: Acute Coronary Syndrome, Part 3: Cardio-Renal Syndrome, Kuala Lumpur, Malaysia, November 29, 2007.
- L136) “Multimarker Strategies in the Management of Cardiovascular Emergencies,” YMCA for Dr. H.F.Ho, Queen Elizabeth Hospital, Hong Kong, SAR, November 30, 2007.
- L137) “Practical Management of Cardiovascular Disease in Patients with Kidney Disease” Williamsburg, Virginia for the 34th Annual Williamsburg Conference on Heart Disease, Williamsburg, VA, December 3, 2007.
- L138) “New Cardiovascular Drugs” 17th Annual Cardiovascular Conference at Beaver Creek” Avon, CO, February 12, 2008.

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- L139) “New Insights into Atherosclerosis and Global CVD Risk,” 17th Annual Cardiovascular Conference at Beaver Creek” Avon, CO, February 12, 2008.
- L140) “Plenary 2 : Mini-Symposia: Acute Kidney Injury (AKI): Pathophysiology: Contrast Nephropathy: Epidemiology and Prognosis” 13th Annual International Conference on Continuous Renal Replacement Therapies, San Diego, CA, February 28, 2008.
- L141) “Heart Failure and Cardio-Renal Syndrome 1: Pathophysiology” 13th Annual International Conference on Continuous Renal Replacement Therapies, San Diego, CA, February 29, 2008.
- L142) “Hemodynamic Monitoring: Principles and Practice” 13th Annual International Conference on Continuous Renal Replacement Therapies, San Diego, CA, February 29, 2008.
- L143) “Cardiovascular Calcification, Potential Strategies in Minimizing Cardiovascular Disease in CKD”, Satellite Symposia at the 57th ACC Annual Scientific Sessions, Chicago, IL, March 30, 2008.
- L144) “Emergency Evaluation of Chest Pain: Building a Better Mousetrap” Olathe Medical Center Annual Heartbeat Symposium, Olathe, KS, April 4, 2007.
- L145) “Interventions and CVD Interactions in Diabetics with Proteinuria” Satellite Symposia (Chairman) Chronic Kidney Disease Interventions: Improving CKD and CVD Outcomes” NKF Clinical Meeting 2008, Dallas, TX, April 5, 2008.
- L146) “Shifting Paradigms in PCI: Controversial Issues in High-Risk Patients” International Symposium (Chairman), Barcelona, Spain, April 10, 2008.
- L147) “Success in Identifying Heart Failure” Satellite Symposia “Managing CVD: What Every Internist Needs to Know” Annual Scientific Sessions of the American College of Physicians, Washington, DC, May 14, 2008.
- L148) “Cardiovascular Calcification in Patients with Chronic Kidney Disease” Satellite Symposia “Cardiovascular Disease in CKD: Strategies for Minimizing Mortality” Annual Scientific Sessions of the American College of Physicians, Washington, DC, May 15, 2008.
- L149) “Clinical Trial Designs in Contrast Induced Acute Kidney Injury,” Third Annual AKIN Conference on Research Initiatives in AKI, Bethesda, MD, June 10-12, 2008.
- L150) “Neutrophil Gelatinase Associated Lipocalin (NGAL)” on Behalf of Inverness Medical, Third Annual AKIN Conference on Research Initiatives in AKI, Bethesda, MD, June 10-12, 2008.

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- L151) “Practical Strategies to Manage Contrast-induced Acute Kidney Injury (CI-AKI): The Evidence and the Controversy” Radiological Society of Taiwan, Taipei, Taiwan, July 17, 2008.
- L152) “Practical Strategies to Manage Contrast-induced Acute Kidney Injury (CI-AKI): The Evidence and the Controversy” Radiological Society of Taiwan, Kaushiung, Taiwan, July 18, 2008.
- L153) “Practical Strategies to Manage Contrast-induced Acute Kidney Injury (CI-AKI): The Evidence and the Controversy” Contrast-Induced Nephropathy Symposium, Professor Yalin Han, MD, Chairwoman of Military Cardiology Society of China, Shenyang, China, July 20, 2008.
- L154) Cardiology Teaching Rounds, with Professor Runlin Gao, Beijing Fuwai Hospital, Beijing, China, July 21, 2008.
- L155) Cardiology Teaching Rounds, with Professor Yujie Zhou, Beijing Anzhen Hospital, Beijing, China, July 21, 2008.
- L156) Cardiology Teaching Rounds with Professor Yundai Chen, General Hospital of Military, Peoples Liberation Army, Beijing, China, July 21, 2008.
- L157) “Practical Strategies to Manage Contrast-induced Acute Kidney Injury (CI-AKI): The Evidence and the Controversy” Contrast-Induced Nephropathy Symposium, Contrast-Induced Nephropathy Symposium, Professor Runlin Gao, Chairman of Chinese Cardiology Society, Beijing, China, July 22, 2008.K
- L158) “New Insights on Accelerated Vascular Calcification in Patients with Kidney Disease” Plenary Session: Ischemic Heart Disease/Risk Assessment/New Treatment Strategies” International Academy of Cardiology 14th World Congress on Heart Disease, Annual Scientific Sessions, Toronto, Ontario, Canada, July 29, 2008.
- L159) “Cardiorenal Syndrome: the Diagnostic Value of Brain Natriuretic Peptide and Neutrophil Gelatinase Associated-Lipocalin in Interventional Cardiology,” Cardiovascular Biomarkers which Enhance Clinical Practice in Emergency Medicine and Cardiology: the State of the Art for Markers of Necrosis, Hemodynamic Stress and Cardiorenal Syndrome, Satellite Symposium to the European Society of Cardiology Annual Scientific Sessions, Munich, Germany, September 2, 2008.
- L160) “Diagnosis and Management of Diabetes, Hypertension, and Acute Dyspnea,” 2008 CVD and CKD Intersection Consensus Conference, Chicago, IL, September 26, 2008.
- L161) “Chronic Kidney Disease and Contrast Nephropathy (Contrast-Induced Acute Kidney Injury [CI-AKI]): From Prognostic Scores to the Latest Preventive Strategies” Complex

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Patients, Complex Lesions, 20th Annual Transcatheter Therapeutics Conference, Washington, DC, October 14, 2008.

- L162) “Chronic Kidney Disease: a CHD Risk Equivalent” 2008 Cardiometabolic Health Congress, Harvard Medical School, Boston, MA, October 19, 2008.
- L163) “Hyperphosphatemia as a Cardiovascular Risk Factor” Nephrology Conference, The Ottawa Hospital, Ottawa, Ontario, Canada, October 28, 2008.
- L164) “Cardiovascular Calcification in Patients with Chronic Kidney Disease” Nephrology Division-Wide Conference, The Ottawa Hospital, Ottawa, Ontario, Canada, October 28, 2008.
- L165) “Hyperphosphatemia and CVD Risk,” Management of Hyperphosphatemia Across the Continuum of CKD, American Society of Nephrology Satellite Symposium, Philadelphia, PA, November 8, 2008.
- L166) “Cardiovascular Calcification” Nephrology Grand Rounds, Humber River Regional Hospital, Toronto, Ontario, Canada, December 9, 2009.
- L167) “Cardiovascular Calcification” Nephrology Grand Rounds, St. Joseph’s Hospital, Toronto, Ontario, Canada, December 9, 2009.
- L168) “Critical Concepts in the Progression of Atherosclerosis” 18th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 9, 2009.
- L169) “New Molecular Targets in the Treatment of Atherosclerosis” 18th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 9, 2009.
- L170) “Sudden Cardiac Death in Patients with Renal Disease” 18th Annual Cardiovascular Conference at Beaver Creek, Beaver Creek, CO, February 12, 2009.
- L171) “Cardiovascular and Renal Implications of Contrast Media” Radiology Grand Rounds, The Kingston Hospital, Queens University School of Medicine, Kingston, Ontario, Canada, March 3, 2009.
- L172) “Recent Evidence into the Pathophysiology of Cardiovascular Calcification in Chronic Kidney Disease,” NKF Symposium 2009 Spring Clinical Meetings, “Exploring Recent Evidence Related to Cardiovascular Calcification and Chronic Kidney Disease”, Nashville, TN, March 27, 2009.
- L173) “Chronic Kidney Disease: Implications For Patients With CAD” Managing the High Risk Coronary Patient, I2 Summit, American College of Cardiology Annual Scientific Sessions, Orlando, FL, March 30, 2009.

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- L174) “BNP and Cardiovascular Disease” Cardiology Grand Rounds, Hospital PróCardíaco, Rio de Janeiro, Brasil, April 14, 2009.
- L175) “Acute Cardiac Effects of Marathon Running” Special Guest Lecture, CLINIMEX - Clínica de Medicina do Exercício, Rio de Janeiro, Brasil, April 14, 2009.
- L176) “Interface entre doença renal e cardiovascular: o rim mata o coração ou o coração mata o rim? Da para evitar esse extermínio?” Terapeutica Cardiovascular International, Hospital Espanhol, Salvador, Brasil, April 17, 2009.
- L177) “A angiotomografia coronária deve ser empregada em todo paciente com doença torácica de risco baixo-moderado?” Terapeutica Cardiovascular International, Hospital Espanhol, Salvador, Brasil, April 17, 2009.
- L178) “Conferencia Internacional: Oportunidades para aperfeiçoar o tratamento da insuficiência cardíaca avançada/descompensada” Terapeutica Cardiovascular International, Hospital Espanhol, Salvador, Brasil, April 17, 2009.
- L179) “Invasive Versus Non-invasive Coronary Angiography: Guidelines for Achieving Optimal Outcomes” Annual Scientific Sessions of the Society for Cardiac Angiography and Intervention, Las Vegas, NV, May 7, 2009.
- L180) “Cardiorenal Syndrome” Moderator, American Society of Nephrology Annual Scientific Sessions, Renal Week 2009, San Diego, CA, October 29, 2009.
- L181) “The Creatinine Changes: Now What?” Cardiorenal Syndromes, Annual Scientific Sessions, AHA, Orlando, FL, November 16, 2009.
- L182) “Cardiorenal Syndromes: Strategies for Success” 19th Annual Cardiovascular Conference at Beaver Creek, Avon, CO, February 6-11, 2010.
- L183) “Cardiomyopathy of Obesity” 19th Annual Cardiovascular Conference at Beaver Creek, Avon, CO, February 6-11, 2010.
- L184) “Why Does Atherosclerosis Calcify: Clinical Implications” 19th Annual Cardiovascular Conference at Beaver Creek, Avon, CO, February 6-11, 2010.
- L185) “Prevention Trials in AKI” 15th International Conference on Continuous Renal Replacement Therapies (CRRT: 2010) Scientific Meeting, Del Coronado, CA, February 24, 2010.
- L186) “Cardiology Trials” 15th International Conference on Continuous Renal Replacement Therapies (CRRT: 2010) Scientific Meeting, Del Coronado, CA, February 24, 2010.

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- L187) “Contrast Nephropathy: Prevention and Management” 15th International Conference on Continuous Renal Replacement Therapies (CRRT: 2010) Scientific Meeting, Del Coronado, CA, February 26, 2010.

- L188) “Lipoprotein-Associated Phospholipase A2 (Control#: 4599)” Symposium: Do New Markers & Genomics Enhance Risk Prediction? Annual Scientific Sessions of the ACC, Atlanta, GA, March 15, 2010.

- L189) “New Insights Into the Role of Heart-Kidney Interactions in the Cardiorenal Syndrome” (Control#: 16660) Symposium: Recognition and Management of the Cardiorenal Syndrome in Advanced Heart Failure, Annual Scientific Sessions of the American College of Cardiology, Atlanta, GA, March 15, 2010.

- L190) “B-Type Natriuretic Peptides in Cardiorenal Syndromes” 5th Annual Turning Science into Caring Symposium, Wiesbaden, Germany, March 25, 2010.

- L191) “CKD and CVD Interaction in KEEP” KEEP Update: the Common Soil of CKD and CVD, NKF Spring Clinical Meetings, Orlando, FL, April 16, 2010.

- L192) “Cardio Renal Intersection, Crossroads to the Future - Novel Coronary Risk Factors” NKF Spring Clinical Meetings, Orlando, FL, April 16, 2010.

- L193) “Diagnostic Workup of suspected heart disease in CKD” NKF Spring Clinical Meetings, Orlando, FL, April 17, 2010.

- L194) “BNP: Beyond Heart Failure (BNP más allá de la insuficiencia cardiaca)”, XIX Chile 2010 Congreso Latinoamericano de Bioquímica Clínica, XVI Congreso Chileno de Química Clínica, Biomarcadores en Enfermedades Cardio-Renales COLABIOCLI 2010, Santiago del Chile, April 21, 2010.

- L195) “Prevention of Cardiorenal Syndromes”, 19th International Vicenza Course on Critical Care Nephrology, Vicenza, Italy, June 10, 2010.

- L196) “La Pandemia de la Obesidad: Que podemos hacer aquí y ahora” “Importancia de la Evaluación previa y el monitoreo cardiaco en rehabilitación cardiaca” “Ergoespiometria: Diagnostico e implicaciones terapéuticas,” Sociedad Colombiana de Cardiología y Cirugía Cardiovascular Fundación Colombiana del Corazón Comité de Prevención y Rehabilitación Cardiovascular Día Mundial del Corazón, Santa Marta, Colombia, September 25, 2010.

- L197) “CKD: A CHD Equivalent” 2010 Cardiometabolic Health Congress (CMHC), Boston MA, October 22, 2010.

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- L198) “Treatment Disparities in Patients with Acute Coronary Syndromes and Kidney Disease” AHA Scientific Sessions 2010, Chicago, IL, November 13, 2010.
- L199) “Integration of Advanced Information Technology into Nephrology Practice” Moderator, at the American Society of Nephrology, Denver, CO, November 21, 2010.
- L200) “Cardiorenal Syndromes” Special Lecture, Mansoura Nephrology and Urology Center, Mansoura, Egypt, November 29, 2010.
- L201) “Neutrophil Gelatinase Associated Lipocalin.” Al Mokhtabar Laboratories, Cairo, Egypt, December 1, 2010.
- L202) “Cardiorenal Syndromes” ACC Williamsburg Conference, Williamsburg, VA, December 5, 2010.
- L203) “Micronutrients and Cardiorenal Disease: Insights into Novel Assessments and Treatment” 13th International Conference on Dialysis, Advances in CKD 2011, Miami, FL, January 26, 2011.
- L204) “Managing High Risk Patients in a i2 Spotlight entitled Cardiac Care Team Spotlight: Approaches for CAD Management” American College of Cardiology 60th Annual Scientific Session and i2 Summit 2011, April 2, 2011, in New Orleans, LA.
- L205) “Lipid Management in Patients with Renal Insufficiency in a ACC Symposium entitled Lipid Management in Special Populations” American College of Cardiology 60th Annual Scientific Session and i2 Summit 2011, April 2, 2011, in New Orleans, LA.
- L206) “KEEP Symposium 2011: KEEP A New Longitudinal Dimension for a New Decade” NKF Spring Clinical Meetings, April 29, 2011, Las Vegas, NV.
- L207) “Disparities of Treatment for ACS and Heart Failure in CKD Patients” 20th International Vicenza Course on Hemodialysis and CKD, June 8, 2011, Vicenza, Italy.
- L208) “AKI: Can We Prevent It?” 20th International Vicenza Course on Hemodialysis and CKD, June 9, 2011, Vicenza, Italy.
- L209) “Measuring Natriuretic Peptides in Acute Coronary Syndromes” American Association of Clinical Chemistry Annual Meeting, Atlanta, GA, July 26, 2011.
- L210) “Biomarkers in Stable Angina and Microvascular Dysfunction”, Emerging Role of Biomarkers in Cardiorenal Syndrome and Acute Coronary Syndrome: Diagnosis Stratification and Management, Siena Italy, September 2, 2011.

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- L211) “Cardiorenal Syndrome Definition and Scope: Cardiac Perspective” 28th National Congress of Nephrology, Hypertension, Dialysis, and Transplantation, Antalya, Turkey, October 20, 2011.
- L212) “Targeted Hypertension Management for Optimal Cardiorenal Outcomes” 28th National Congress of Nephrology, Hypertension, Dialysis, and Transplantation, Antalya, Turkey, October 22, 2011.
- L213) “The KEEP Experience” 3rd International Symposium on Albuminuria – The Prognostic Role of Albuminuria: Impact on Kidney and Cardiovascular Outcomes, Groningen, Netherlands, December 1, 2011.
- L214) “Cardiorenal Syndromes” Cardiology Guest Lecture, University of Chicago, Pritzker School of Medicine, Chicago, IL, January 18, 2012.
- L215) “Diagnosis of Cardiovascular Disease in CKD” 14th international conference on dialysis, advances in CKD 2012, Palm, Harbor, FL, January 26, 2012
- L216) “Acute Kidney Injury Guidelines” KDIGO Clinical Practice Conference: KDIGO Guidelines on Acute Kidney Injury, Glomerulonephritis, and Anemia, Shanghai, China, February 5, 2012
- L217) “Galectin-3: A Novel Blood Test for the Evaluation and Management of Heart Failure” Cardiology Grand Rounds, University of Arkansas for Medical Sciences, Little Rock, Arkansas, February 8, 2012
- L218) “Contrast-Induced Acute Kidney Injury” 17th Annual CRRT 2012, Acute Kidney Injury Controversies, Challenges, and Solutions, San Diego, CA February 15, 2012
- L219) “Recent Trials in the Prevention of Contrast-Induced AKI: Importance of Emerging Biomarkers” 17th Annual CRRT 2012, Acute Kidney Injury Controversies, Challenges, and Solutions, San Diego, CA February 17, 2012
- L220) “Role of Galectin-3 in Heart Failure” Joint American Association of Cardiologists of Indian Origin and ACC Dinner Symposium, American College of Cardiology Scientific Sessions 2012, Chicago, IL, March 25, 2012
- L221) “Bariatric Surgery: A Cure for Obesity?” American College of Cardiology Scientific Sessions 2012, Joint Symposium of the American Association of Clinical Endocrinologists and the ACC: Cardiologists as Endocrinologists – Emerging Management of the Diabetic Patient, Chicago, IL, March 26, 2012
- L222) “Practical Management of Obesity for the Cardiologist” 48th Annual Robert M. Jeresaty Cardiovascular Symposium, Hartford, CT, May 3, 2012

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- L223) "Prevention of Cardiovascular Events: Beyond Statins" 48th Annual Robert M. Jeresaty Cardiovascular Symposium, Hartford, CT, May 3, 2012
- L224) "Contrast Media and Patient Safety: The Clinical Impact" Swiss Congress of Radiology, Zurich, Switzerland, May 31, 2012
- L225) "Importance of Methodological Rigor in CI-AKI Meta-Analyses" 48th Congresso Nazionale Italian Society of Radiology (SIRM), Torino, Italy, June 2, 2012
- L226) "Chronic Kidney Disease and Heart Failure" 2012 Cardiometabolic Health Congress (CMHC) Boston, MA, October 12, 2012
- L227) "Chronic Kidney Disease and Acute Myocardial Infarction" CKD a Recipe for CVD Disaster, Kidney Week, American Society of Nephrology, San Diego, CA, October 30, 2012
- L228) "Epidemiology and Pathophysiology of Coronary Artery Disease in Chronic Kidney Disease" Scientific Sessions 2012, AHA, Los Angeles, CA, November 5, 2012
- L229) "The Cardiorenal Syndrome" Acute Dialysis Quality Initiative 11: Cardiorenal Syndromes, Venice, Italy, November 30, 2012
- L230) "Cardiorenal Syndromes" Cardiology Grand Rounds, University of Missouri School of Medicine, Columbia, MO, December 20, 2012
- L231) "Diagnosis and Management of Coronary Disease in Patients with Kidney Disease" Internal Medicine Grand Rounds, University of Missouri School of Medicine, Columbia, MO, December 20, 2012
- L232) "The Hypertension Epidemic: Are We Any Further Ahead?" 22nd Annual Cardiovascular Conference at Beaver Creek, Avon, CO, February 9-16, 2013
- L233) "Cardiorenal Syndromes: The Cardiac Perspective" Inaugural Cardio Renal Society of America (CRSA), 14th Annual Southwest Nephrology Conference (SWNC), Chandler, AZ, March 2, 2013
- L234) "Managing Hyponatremia in Cardiorenal Syndromes" Satellite Symposia to the NKF Spring Clinical Meetings, Orlando, FL, April 3, 2013
- L235) "Session Title: Debate: To Screen or Not to Screen for CKD--PRO? NKF Spring Clinical Meetings, Orlando, FL, April 5, 2013

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- L236) “Galectin-3: A Novel Biomarker for the Assessment and Management of Heart Failure” Heart Failure Conference, University of Pittsburgh Medical Center, Pittsburgh, PA, May 28, 2013
- L237) “The Kidney in Heart Failure” 31st International Vicenza Course on Critical Care Nephrology, June 11-14, 2013, Vicenza, Italy
- L238) “Contrast-Induced Acute Kidney Injury” 31st International Vicenza Course on Critical Care Nephrology, June 11-14, 2013, Vicenza, Italy
- L239) “Novel Biomarkers in the Prognosis and Management of Heart Failure” BUMC Medicine Grand Rounds, August 20, 2013, Dallas, TX
- L240) “Cardiorenal Syndromes: New Insights into Combined Heart and Kidney Failure” Cardiology Grand Rounds, University of Virginia Medical Center, August 26, 2013, Charlottesville, VA
- L241) “Major Advances in the Treatment of Atherosclerosis: New Options for Patients with Familial Hypercholesterolemia and Those Intolerant to Conventional Lipid Lowering Therapy” Cardiology Update, University of Missouri School of Medicine, September 14, Columbia, MO
- L242) “Keynote Address: Recent Advances in the Assessment of Acute Kidney Injury with Neutrophil Gelatinase Associated Lipocalin” 47th Brazilian Congress of Clinical Pathology and Laboratory Medicine, September 23, 2013, Sao Paulo, Brazil.
- L243) “Advancements in Cardiometabolic Risk Assessment: Expert Analysis of Recent Evidence and Outcomes” 2013 Cardiometabolic Health Congress, October 2, 2013, Boston, MA.
- L244) “Keynote Address: Cardiorenal Syndromes: New Insights to Patients with Combined Heart and Kidney Failure” Fourth Italian Great Network Congress, Focus on Innovation and Translational Research in Emergency Medicine, Sapienza Universita di Roma, October 14-18, 2013, Rome, Italy.
- L245) “Practical Experience with Galectin-3” Fourth Italian Great Network Congress, Focus on Innovation and Translational Research in Emergency Medicine, Sapienza Universita di Roma, October 14-18, 2013, Rome, Italy.
- L246) “Using Novel Biomarkers in the Assessment and Management of Heart Failure” Bon Secours Cardiovascular Conference, October 25, 2013, Williamsburg, VA

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- L247) “Detection and Consequences of Iron Deficiency Anemia in CKD Patients” Session Title: The Role of Iron in the Optimization of Anemia Management in CKD, American Society of Nephrology, Kidney Week, November 9, 2013, Atlanta, GA
- L248) “Bench to Bedside: What Happens to the Physiologic Systems After an Acute Bout of High Intensity/Volume Exercise?” Session Title: Cardiovascular Seminar entitled Potential Cardiotoxicity of Extreme Endurance Exercise, Annual Scientific Sessions of the AHA, November, 20, 2013, Dallas, TX.
- L249) “Atrasentan for the treatment of diabetic nephropathy: how to control the risk of heart failure?” Session Title: “Lessons Learned from First Post FDA Guidance Case Studies of Diabetes CV Outcomes Trials, 10th Global CardioVascular Clinical Trialists (CVCT) Forum, December 7, 2013, Paris, France.
- L250) “Reflection: Biomarker-based modeling tools: safer drugs and faster development?” A workshop initiated by the TI-Pharma Escher project for academia, industry, and the European Medicines Agency, January 24, 2014, Amsterdam, the Netherlands.
- L251) “Focus on lipids: HDL and Its Associated Lipoproteins in Cardiac and Renal Disease” Changing Paradigms in Acute Kidney Injury: From Mechanisms to Management Sponsored by UAB/UCSD O’Brien Center for AKI Research, 19th International Conference on Advances in Critical Care, CRRT 2014, International Society of Nephrology, Acute Kidney Injury Network, March 4-7, 2014, San Diego, CA.
- L252) “Cardiac and Renal Fibrosis in Chronic Cardiorenal Syndromes” Targeting Recovery from Acute Kidney Injury:, 19th International Conference on Advances in Critical Care, CRRT 2014, International Society of Nephrology, Acute Kidney Injury Network, March 4-7, 2014, San Diego, CA.
- L253) “Statins for AKI: Friend or Foe” Controversies in Critical Care Nephrology:, 19th International Conference on Advances in Critical Care, CRRT 2014, International Society of Nephrology, Acute Kidney Injury Network, March 4-7, 2014, San Diego, CA.
- L254) “Managing Heart Failure and Cardiorenal Syndrome” Workshop, 19th International Conference on Advances in Critical Care, CRRT 2014, International Society of Nephrology, Acute Kidney Injury Network, March 4-7, 2014, San Diego, CA.
- L255) “ST2: A Novel Biomarker in the Assessment and Management of Heart Failure” 2nd Annual Cardio Renal Society of America (CRSA), 15th Annual Southwest Nephrology Conference (SWNC), Ft. McDowell, AZ, March 8, 2014.
- L256) “Cardiac and Renal Fibrosis in Chronic Cardiorenal Syndromes” 2nd Annual Cardio Renal Society of America (CRSA), 15th Annual Southwest Nephrology Conference (SWNC), Ft. McDowell, AZ, March 8, 2014.

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- L257) “New Approaches to the Management of Cardiorenal Syndromes” 2nd Annual Cardio Renal Society of America (CRSA), 15th Annual Southwest Nephrology Conference (SWNC), Ft. McDowell, AZ, March 8, 2014.
- L258) “My New Favorite Biomarker: Galectin-3” 2014 UCSD Biomarkers in Clinical Practice Symposium, La Jolla, CA, April 5, 2014.
- L259) “Changing Profile of Chronic Hyperkalemia” NKF Spring Clinical Meetings, Las Vegas, NV, April 24, 2014.
- L260) “The Next Generation of Screening for Kidney Disease” NKF Spring Clinical Meetings, Las Vegas, NV, April 25, 2014.
- L261) “Cardiorenal Syndromes” Cardiology, Diabetes & Nephrology at the Limits, Royal College of Physicians, London, UK, April 26, 2014.
- L262) “Acute Cardiorenal Syndromes: New Insights into Combined Heart and Kidney Failure” Actual Problems of Extracorporeal Blood Purification in Intensive Care, Russian Scientific Society of Specialists in Extracorporeal Blood Purification, Bakoulev Scientific Center for Cardiovascular Surgery of the Russian Academy of Medical Sciences, Moscow, Russia, May 22, 2014.
- L263) "Fibrosis in the Heart and Kidneys in the Pathogenesis of Chronic Cardiorenal Syndromes" Actual Problems of Extracorporeal Blood Purification in Intensive Care, Russian Scientific Society of Specialists in Extracorporeal Blood Purification, Bakoulev Scientific Center for Cardiovascular Surgery of the Russian Academy of Medical Sciences, Moscow, Russia, May 23, 2014.
- L264) “Hyperkalemia: Old Foe with New Faces” 51st European Renal Association – European Dialysis and Transplantation Association Congress, Amsterdam, the Netherlands, June 2, 2014.
- L265) “Contrast Induced Complications in the Cath Lab” Transcatheter Cardiovascular Therapeutics (TCT) Russia, Moscow, Russia, June 16, 2014.
- L266) “The RAASi Debate: Should RAAS Continue with a Declining GFR?: Will the Path be Clearer” Co-Chair, European Society of Cardiology, Barcelona, Spain, August 31, 2014.
- L267) “Novel Markers of Acute and Chronic Kidney Injury,” Where Inflammation Meets Lipids: Broad Based Strategies for Risk Reduction, Cleveland Heart Labs, Cleveland, OH, September 12, 2014.

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- L268) “Advances in the Understanding of Acute and Chronic Cardiorenal Syndromes: Pathophysiological Crosstalk of Multiple Metabolic and Neurohormonal Systems” 41st Williamsburg Cardiovascular Conference, Williamsburg, VA, December 7, 2014.
- L269) “CHADS, CHADS-VASc, HAS-BLED, What Does it Mean and How Do We Use It? Atrial Fibrillation Session, Dallas-Leipzig Valve 2104, Dallas, TX, December 11, 2014.
- L270) “Soup-to-Nuts Renal Failure: Caring for the Patient with Kidney Injury” Society of Critical Care Medicine, Phoenix, AZ, January 19, 2015.
- L271) “RAASi Optimization in Heart Failure” 2nd Annual Cardiorenal Society of America Meeting, Phoenix, AS, February 28, 2015.
- L272) “Cardiac Surgery Associated Acute Kidney Injury” Association of Physician Assistants in Cardiac Surgery, Las Vegas, NV, March 3, 2015.
- L273) “The Potassium Challenge in CKD: Managing Acute and Chronic Hyperkalemia: Novel Polymer-Based Potassium Binders: Clinical Evidence” NKF Spring Clinical Meetings, March 27, 2015.
- L274) “KEEP Healthy: Insights into CKD Care” NKF Spring Clinical Meetings, March 28, 2015.
- L275) “The Heart of the Matter” NKF Spring Clinical Meetings, March 28, 2015.
- L276) “Literature Review: CVD” NKF Spring Clinical Meetings, March 28, 2015.
- L277) “Biomarkers of Kidney and Heart Injury in Cardiorenal Syndrome” Cardioneurology 2015, Rome, Italy, April 16, 2015.
- L278) “AKI after Acute Myocardial Infarction: Contrast, Organ Crosstalk and Complications” 33rd Vicenza Course on Critical Care Nephrology in Vicenza, Italy, June 9-12, 2015.
- L279) “A New Mechanism of Action for Addressing Hyperkalemia: New Data on Non-Polymer Hyperkalemia Therapies” 33rd Vicenza Course on Critical Care Nephrology in Vicenza, Italy, June 9-12, 2015.
- L280) “Lp-PLA2 as a marker of Vascular Inflammation and CHD Risk Assessment” Symposium: Advances in Laboratory Testing for Coronary Heart Disease; The New PLAC Test for Lp-PLA2 Activity, American Association of Clinical Chemistry Annual Meeting, Atlanta, GA, June 29, 2015.
- L281) “Galectin-3 in the Prognosis and Management of Heart Failure” American Association of Clinical Chemistry Annual Meeting, Atlanta, GA, June 29, 2015.

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- L282) “Cardio-Renal Syndrome and Clinical Implications” AKI from Pathophysiology to Clinical Implications, Global Research on Acute Conditions Team (GREAT) Annual Meeting, Rome, Italy, September 5, 2015.
- L283) “Lp-PLA2 and Testing for Primary Prevention Risk Assessment” 2015 Cardiometabolic Health Congress, Harvard Medical School, Boston, MA, October 22, 2015.
- L284) “Heart and Kidney: a Dangerous Liaison” Comorbidities in Heart Failure: From Guidelines to Clinical Practice, 775 Anniversary University of Sienna, Sienna, Italy, October 29, 2015.
- L285) “Role of BNP, Pro-BNP, and Elevated Left Ventricular Mass in Cardiorenal Syndrome” American Society of Nephrology Kidney Week, San Diego, CA, November 6, 2015.
- L286) “How to Use Urine Thromboxane B2 to Select and Monitor Aspirin Therapy” Moderator, Scientific Sessions 2015, AHA, Orlando, FL, November 10, 2015.
- L287) “Putting it All Together: How to Use Urine 11-Dehydrothromboxane B2 In Clinical Practice” Scientific Sessions 2015, AHA, Orlando, FL, November 10, 2015.
- L288) “Neurogenic Orthostatic Hypotension” Moderator, Scientific Sessions 2015, AHA, Orlando, FL, November 10, 2015.
- L289) “Cardiac Cachexia” Managing Disease Related Lean Body Mass Loss Through Clinical and Nutritional Interventions, The Sackler Institute for Nutrition Science The New York Academy of Sciences, New York, NY, December 4, 2015.
- L290) “The Devastating Consequences of Systemic Hypertension and What To Do About It?” 42st Williamsburg Cardiovascular Conference, Williamsburg, VA, December 6-8, 2015.
- L291) “The Impact and Management of Malnutrition in Patients with Heart Failure” Heart Failure University 2015, Conference Co-Chair, Los Angeles, CA, December 11-13, 2015.
- L292) “Acute and Chronic Cardiovascular Effects of Hyperkalemia: New Insights Into Prevention and Clinical Management” Heart Failure University 2015, Conference Co-Chair, Los Angeles, CA, December 11-13, 2015.
- L293) “Lipoic Acid in the Prevention of Acute Kidney Injury” 21st International Conference on Continuous Renal Replacement Therapies CRRT 2016, San Diego, CA, February 16-18, 2016.
- L294) “Novel Approaches for Recognition and Management of Life Threatening Complications of AKI and CKD” 21st International Conference on Continuous Renal Replacement Therapies CRRT 2016, San Diego, CA, February 16-18, 2016.

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- L295) “Making Iodinated Contrast Less Nephrotoxic with Cyclodextrin” 21st International Conference on Continuous Renal Replacement Therapies CRRT 2016, San Diego, CA, February 16-18, 2016.
- L296) “Cardiorenal Syndrome” 4th Annual Cardio-Renal Metabolic Conference, Cardiorenal Society of America, Phoenix, AZ, March 13, 2016.
- L297) “Cardiorenal Syndromes Identification: Prevention and Management of CI-AKI” China Interventional Therapeutics (CIT), Beijing, Shanghai Zhong Shan Hospital, Shanghai, The 2nd Affiliated Hospital of Zhejiang University, Hangzhou, Xi Jing Hospital, Xi’an, Nanjing 1st Hospital, Nanjing, Peoples Republic of China, March 14-21, 2016.
- L298) “Cardiorenal Syndromes” Keynote Address, Inaugural Cardio-Renal Connections Meeting, San Antonio, TX , April 16, 2016.
- L299) “Galectin-3 in the Prognosis and Management of Heart Failure” American Association of Clinical Chemistry Annual Scientific Meeting, Philadelphia, PA, August 1, 2016.
- L300) Hemodialysis University, “Is It Heart Failure or Fluid Overload?”, Chicago, IL, September 10, 2016.
- L301) “Novel Agents for the Treatment of Hyperkalemia” Heart Failure Society of America Annual Scientific Meeting, Orlando, FL, September 18, 2016.
- L302) Symposium “Hyperkalemia in the Emergency Department: Updates on the Current Management of a Complex Condition.” “Novel Agents for the Prevention and Treatment of Hyperkalemia” American College of Emergency Physicians Scientific Assembly, Las Vegas, NV, October 14, 2016
- L303) Moderator “CVD in Patients with CKD: Update from the CRIC Study” Annual Scientific Sessions of the AHA, New Orleans, LA, November 13, 2016
- L304) Program Chairman “A Night at the Museum: Inaugural Symposium of the Cardiorenal Society of America Transcending the Dinosaurs: Guiding AKI Prevention using next-gen biomarkers: Real World Experiences from modern practices” satellite Symposium at American Society of Nephrology Kidney Week, Field Museum, Chicago, IL, November 18, 2016
- L305) “Pathobiologic Systems Involved in Cardiorenal Disease” 43rd Williamsburg Cardiovascular Conference, Williamsburg, VA, December 3-5, 2016

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- L306) “Cardiac Cachexia” Heart Failure University, MedReviews LLC, Los Angeles, CA, December 10, 2016
- L307) “Is There a Role for Bariatric Surgery in Heart Failure Patients with Obesity?” Scientific Sessions 2017, American College of Cardiology , Washington, DC, March 18, 2017
- L308) “Vascular and Cardiac Hypertrophy in Fabry Disease” 5th Annual Fabry Nephropathy Update, Mexico City, Mexico, April 26, 2017
- L309) “Introduction to Cardiorenal Medicine” Cardiorenal University, Anaheim, CA, May 18, 2017
- L310) “Sudden Death in End-Stage Renal Disease” Cardiorenal University, Anaheim, CA, May 18, 2017
- L311) “Cardiorenal Syndromes and Heart Failure” Conference Chair, Disease Global Outcomes (KDIGO) Controversies Conference on Heart Failure in Chronic Kidney Disease, Athens, Greece, May 25-28, 2017
- L312) “Vadadustat Does Not Prolong Corrected QT Interval In A Thorough QTC Study In Healthy Subjects” 54th ERA-EDTA Congress, Madrid, Spain, June 3-6, 2017
- L313) “Cardiorenal Syndromes” 1st Annual Heart iN Diabetes: Where the Heart, Kidney, and Diabetes Meet in Clinical Practice, Philadelphia, PA, July 14-16, 2017
- L314) “Cardiovascular Disease in Patients with Chronic Kidney Disease: A Serious Link” TOP 2017--Target Organ Protection Conference, Bangalore, India, August 11, 2017
- L315) “Statin Therapy to Prevent Onset and Progression of Vascular Disease” TOP 2017--Target Organ Protection Conference, Bangalore, India, August 11, 2017
- L316) “Keynote Address: Cardiorenal Society of America” 5th Annual Scientific Meeting of the Cardiorenal Society of America, Phoenix, AZ, October 6, 2017
- L317) “Cardiovascular Benefits of Home Hemodialysis” Addressing Unmet Needs in Dialysis: Cardiovascular Care and Volume Control Symposium, Kidney Week 2017 American Society of Nephrology, New Orleans, LA, November 4, 2017
- L318) “CIEDs in ESRD Patients: What Are the Long-Term Data?” Kidney Week 2017 American Society of Nephrology, New Orleans, LA, November 4, 2017
- L319) “Cardiovascular Seminar Cardiorenal Syndrome: Who hurts who?” AHA Scientific Sessions 2017, Anaheim, CA, November 14, 2017

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- L320) “Cardiac and Renal Fibrosis in CRS” AHA Scientific Sessions 2017, Anaheim, CA, November 14, 2017
- L321) Chair, Inaugural Cardiometabolic University and Nutrition Academy “The Skinny on Weight Loss: Practical Considerations for the Cardiovascular Specialist” MedReviews, Westlake, TX, December 1-3, 2017
- L322) “Clinical Laboratory Advancements in Cardiometabolic Disease: Screening, Diagnosis, Prognosis, and Management” 44th Annual Williamsburg Conference on Heart Disease, Williamsburg, VA, December 4, 2017
- L323) “The Skinny on Weight Loss: Practical Approaches for the Cardiovascular Specialist” Cardiometabolic University 2017, Conference Chair, Dallas, TX , December 1-3, 2017
- L324) “Diagnosis, Evaluation, and Role of Biomarkers in Heart Failure” Heart Failure University 2017, Conference Co-Chair, Los Angeles, CA, December 10-12, 2017
- L325) “Biomarkers of Kidney Dysfunction and Cardiorenal Syndrome” University of California at San Diego 14th Annual Biomarkers in Heart Failure and Acute Coronary Syndromes: Diagnosis, Treatment and Devices, San Diego, CA, March 2, 2018
- L326) “What do I do to Prevent Contrast Induced Renal Injury” 23rd International Conference on Continuous Renal Replacement Therapies CRRT 2018, San Diego, CA, March 8, 2018
- L327) “AKI in the patient with Cancer” 23rd International Conference on Continuous Renal Replacement Therapies CRRT 2018, San Diego, CA, March 8, 2018.
- L328) “CKD-Related Anemia and Cardiac Complications” NKF Spring Clinical Meetings, Austin, TX April 14, 2018
- L329) “Principles of Distributive Shock” Cardiorenal Society of America National Grand Rounds Series, Boston, MA, April 30, 2018
- L330) “Biomarkers with More Muscle: Moving Beyond Serum Creatinine to Define Cardiorenal Syndrome in HF” Heart Failure Society of American Annual Scientific Sessions, Nashville, TN, September 15, 2018
- L331) “Heart Failure in Cardiorenal Syndrome: Updates on Biomarkers” Cardiorenal Society of America Annual Scientific Meeting, Phoenix, AZ, October 6, 2018
- L332) “Novel Approaches in Lowering LDL-C” Cardiorenal Society of America Annual Scientific Meeting, Phoenix, AZ, October 6, 2018

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- L333) “What Do We Know About Cardiorenal Physiology? An Overview” American Society of Nephrology Kidney Week, San Diego, CA, October 26, 2018
- L334) “Prevention of Heart Failure: The Next Frontier” Cardiometabolic Health Conference, Boston, MA, October 27, 2018
- L335) “AKI and Heart Failure: How to Manage Compared to the General Population” Cardiometabolic Health Conference, Boston, MA, October 27, 2018
- L336) “SGLT-2 Inhibitors and Cardio-renal Outcomes: Mechanistic Role and Rationale for Treatment of Heart Failure” American Heart Association Annual Scientific Sessions, Chicago, IL, November 10, 2018
- L337) “Obesity and Heart Disease” 44th Annual Williamsburg Conference on Heart Disease, Williamsburg, VA, December 4, 2018
- L338) “Current Concepts in Hypertension Management” University of Texas Health Science Center, Tyler, TX, January 15, 2019
- L339) “Managing the Heart Failure Patient with Worsening Renal Function (WRF)” 24th International Conference on Continuous Renal Replacement Therapies CRRT 2019, San Diego, CA, February 28, 2019
- L340) “Cardiorenal Syndrome: What Have We Learned?” 24th International Conference on Continuous Renal Replacement Therapies CRRT 2019, San Diego, CA, February 28, 2019
- L341) ” Debate: Biomarker Guided Heart Failure Therapy: Con: Neuropeptides; ST2” 15th Annual USCD Biomarkers in Heart Failure and Acute Coronary Syndromes, Diagnosis, Treatment & Devices, La Jolla, CA March 1, 2019
- L342) “Cardiorenal Syndromes” Cardioneurology Congress, Rome, March 12 to 14, 2019
- L343) “Iron and Heart Failure” Cardiometabolic Health Congress West meeting in Phoenix, AZ on Saturday, May 4, 2019
- L344) “Up to Date Management of Arrhythmias in Dialysis Patients” National Kidney Foundation Spring Clinical Meetings, May 11, 2019
- L345) “Lipids in Chronic Kidney Disease” National Kidney Foundation Spring Clinical Meetings, May 11, 2019
- L346) “Cardiorenal Syndromes” Helen Dunham Cardio-Renal Lecture and Cardiovascular Grand Rounds, Brigham and Women’s Hospital, Boston, MA, May 23, 2019

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- L347) “Chronic Kidney Disease as a Cardiovascular Risk State” Helen Dunham Cardio-Renal Lecture and Cardiovascular Grand Rounds, Brigham and Women’s Hospital, Boston, MA, May 23, 2019
- L348) “Biomarkers and Assessment of Cardiac Function In Fabry Cardiomyopathy” 6th Update on Fabry Disease: Biomarkers, Progression and Treatment Opportunities, Prague, Czech Republic, May 26-28, 2019
- L349) “Contrast-Induced Acute Kidney Injury” 37th Vicenza Course on AKI &CRRT, Vicenza, Italy, May, 28-30 2019
- L350) “Cardiac Biomarkers in AKI” 37th Vicenza Course on AKI &CRRT, Vicenza, Italy, May, 28-30 2019
- L351) “Risk Mitigation in the Cardiac Catheterization Laboratory” 37th Vicenza Course on AKI &CRRT, Vicenza, Italy, May, 28-30 2019
- L352) “Pathophysiology and Current Concepts in Classification” Clinical Practice Clinical Science Track: Treatment of Cardiorenal Syndrome, American Heart Association Hypertension Scientific Sessions, New Orleans, LA, Sept 8, 2019
- L353) “Cardiovascular Genetics” 44th Annual Williamsburg Conference on Heart Disease, Williamsburg, VA, December 9, 2019
- L354) “Cardiorenal Syndromes” 17th World Congress on Insulin Resistance, Diabetes & Cardiovascular Disease (WCIRDC), Los Angeles, CA, December 4-7, 2019
- L355) “Cardiorenal Syndromes” Internal Medicine Grand Rounds, Eastern Virginia College of Medicine, Norfolk, VA, February 19, 2020
- L356) "Keynote Address: Prevention of Heart and Kidney Disease” Annual Cardio Renal Metabolic Conference, Cardiorenal Society of America, Phoenix, AZ March 6, 2020
- L357) “Cardioprotective Effects of Antidiabetic Medications: Focus on Sodium-Glucose Transporter-2 Antagonists” Annual Cardio Renal Metabolic Conference, Cardiorenal Society of America, Phoenix, AZ March 7, 2020
- L358) “Fabry Disease: A Unique Cardiorenal Model” Annual Cardio Renal Metabolic Conference, Cardiorenal Society of America, Phoenix, AZ March 7, 2020
- L359) “Biomarkers in Heart and Kidney Disease: Practical Applications” Annual Cardio Renal Metabolic Conference, Cardiorenal Society of America, Phoenix, AZ March 7, 2020

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- L360) “Expert Briefing from ADA 2020 Select Sessions: Update on Heart Failure for the Diabetologist & Cardiorenal–Metabolic Axis in Diabetes” American Diabetes Association, June 14, 2020
- L361) “CKD, CHD and Hyperkalaemia: Clinical Outcomes, Morbidity and Mortality” American College of Cardiology - American Society of Nephrology Masterclass September 11, 2020
- L362) “RAASi Enabling in Cardiology Practice - Traditional vs New Potassium Binders; Potassium Binders for Treatment of Hyperkalaemia in HF” American College of Cardiology - American Society of Nephrology Masterclass September 11, 2020
- L363) “Optimizing Transitions from Hospital to Home: Best Practices for Reducing Readmissions in Heart Failure” Hospital Management Summit, October 3, 2020.
- L364) “Assessment and Management of Hyperkalemia in the Hospital Setting: Optimizing Patient Outcomes” Hospital Management Summit, October 3, 2020.
- L365) “Navigating the Challenges of Cardio-Renal Syndrome” 7th Annual Kansas Cardiovascular Symposium, October 10, 2020
- L366) “Management Considerations for Heart Failure in CKD” American Society of Nephrology Kidney Week 2020, October 24, 2020
- L367) “Pathophysiologic Basis and Rationale for Early Ambulatory Treatment of SARS-CoV-2 (COVID-19), SciInov, November 2, 2020
- L368) “CV and Renal Benefits with new anti-diabetes medications: Potential Mechanisms” CReDO Conferences Middle East North Africa (MENA) 2020, November 6, 2020
- L369) “Consequences of Withholding GDMT for Heart Failure in CKD: One Step Forward, Two Steps Back” AHA 2020 November 16, 2020
- L370) “Early Ambulatory Treatment for SARS-CoV-2 (COVID-19)” Early Outpatient Treatment: An Essential Part of a COVID-19 Solution. US. Senate Committee on Homeland Security and Governmental Affairs, Washington DC November 19, 2020
- L371) “Pathophysiological Basis & Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection” 18th Annual World Congress Insulin Resistance Diabetes & Cardiovascular Disease, December 3, 2020

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INTERNAL COMMITTEE POSITIONS

- 1) Member, Henry Ford Medical Group Hypertension Control Committee, 1998.
- 2) Ranking Member and Presenter, HFHS Institutional Review Board, 1998-2000.
- 3) Member, HFHS Teaching and Education Committee, Co-Chair of the Research Subcommittee, 1999-2000
- 4) Member, HFHS Graduate Medical Education Committee, 1999-2000.
- 5) Member, HFHS, Internal Medicine Residency Selection Committee, 1998-2000.
- 6) Chair, HFHS, Cardiovascular Diseases Fellowship Program Selection Committee, 1999-2000.
- 7) Co-Chair, HFHS, Information Technology and Medical Records Committee, 1999-2000.
- 8) Member, HFHS Department of Internal Medicine, Research Committee, 1999-2000.
- 9) Member, UMKC Adult Health Sciences Institutional Review Board, 2001-2002
- 10) Member, UMKC, Cardiovascular Diseases Fellowship Program Selection Committee, 2000-2002
- 11) Member, Truman Medical Center (TMC) Information Technology Steering Committee, 2001-2002.
- 12) Member, WBH Diabetes Research Center Steering Committee, 2002-2003
- 13) Chairperson, WBH Staff Privileges Appeals Committee, March 31, 2004
- 14) Chairperson, WBH Search Committee for Medical Director of Transplantation Medicine, 2005-2006
- 15) WBH Research Institute Board of Governors, board member, 2007-2010
- 16) Oakland University William Beaumont School of Medicine, Medical Student Committee (founding) for development of Liaison Committee on Medical Education (LCME) application, 2007-2010
- 17) St. John Providence Health System Graduate Medical Education Steering Committee (Chair), 2010 to 2013

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- 18) St. John Providence Health System Research Leaders Committee, Chair, 2010 to 2012; Co-Chair 2012 to 2013
- 19) Ascension Michigan Research Affinity Group, Chair, 2010 to 2012; Co-Chair 2012 to 2013
- 20) St. John Providence Health System Executive Committee, 2011 to 2013
- 21) St. John Providence Health System Guidelines Committee, 2012 to 2013
- 22) St. John Providence Health System Presidents Council, 2012 to 2013
- 23) St. John Providence Health System Electronic Medical Record Meaningful Use Steering Committee, 2013
- 24) BUMC Graduate Medical Education Committee, 2014 to present
- 25) BUMC Internal Medicine Residency Program Clinical Competency Committee, 2014 to present
- 26) BUMC Clinical Cardiology Fellowship Program Clinical Competency Committee, 2014 to present
- 27) BUMC Founding Member, Department of Molecular Pathology and Medicine, 2016 to present
- 28) BUMC Precision Medicine Executive Committee, 2016 to present
- 29) BUMC COVID-19 Therapeutic Task Force 2020

EXTERNAL COMMITTEE POSITIONS

- 1) Member, AHA National Women's Heart Disease and Stroke Campaign, Healthcare Provider Sub-Group, Dallas, TX, 1998-1999
- 2) Member, AHA, Chronic Coronary Disease in the Elderly National Database Planning Committee, Dallas, TX, 1998-2000
- 3) Chair, Michigan Chapter of the American College of Cardiology, Annual Mini-Board Review, 1999-2000
- 4) Member, Michigan Chapter of the American College of Cardiology, Annual Meeting Planning Committee, 1999-2000

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- 5) Member, National Kidney Disease Outcomes Quality Initiative (K/DOQI) Clinical Practice Guidelines Committee on Chronic Kidney Disease, Andrew S. Levey, MD, Chair, 2001-2002
- 6) Member, K/DOQI Learning System (KLS)TM Advisory Board, NKF, New York, NY, 2003 to 2010
- 7) Member, International EECF Patient Registry Working Group, 2003-2008.
- 8) Counselor at large, Michigan Chapter of the American College of Cardiology, 2004-2006
- 9) Member, Planning Committee, AHA, Prevention VIII Conference: Kidney Disease, Hypertension, and Cardiovascular Disease, January 26-28, 2006, Orlando, FL
- 10) Chair, Contrast-Induced Nephropathy (CIN) Working Group Consensus Panel, (international, multispecialty, consensus panel with published findings) 2004-2006. Published in *Am J Cardiol* 2006 Vol 98(6)
- 11) Workgroup Member, Kidney Disease Improving Global Outcomes (KDIGO), United States Representative, Amsterdam, Netherlands, 2004, 2006
- 12) Member, Kidney Disease Improving Global Outcomes (KDIGO) Group for the development of Clinical Practice Guidelines for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease Related Mineral and Bone Disorders (CKD-MBD), Paris, France, 2007-2008
- 13) Board of Directors Member, Kidney Disease Improving Global Outcomes (KDIGO), United States Representative, Brussels, Belgium, 2007-2010
- 14) Workgroup Member, The Sixth International Acute Dialysis Quality Initiative (ADQI) Consensus Conference VI: Acute Kidney Injury in Cardiac Surgery, Vicenza, Italy May 27 – 28, 2007
- 15) Workgroup Leader, Prevention: The Seventh International Acute Dialysis Quality Initiative (ADQI) Consensus Conference VII: Cardiorenal Syndrome, Venice, Italy, September 4-5, 2008, with publication in *Nephrology, Dialysis, and Transplantation*, 2010.
- 16) Chairman, Natriuretic Peptide Testing in Acute Coronary Syndromes Consensus Panel, with published findings in *Reviews in Cardiovascular Medicine* 2010, Dallas, TX, March 2, 2010
- 17) Scientific Advisory Board, NKF, New York, NY, 2010 to present
- 18) Scientific Advisory Board, Cardiorenal Society of America, Phoenix, AZ, 2012 to present

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- 19) Workgroup Member, “Cardiovascular Disease in CKD: What is it and what can we do about it?” Kidney Disease Improving Global Outcomes (KDIGO), October 29-31, 2010, London, England.
- 20) Chairman, “Cardio-Renal Syndromes II: from pathophysiology to therapy” Eleventh Consensus Conference Cardio-Renal Syndromes II November 30 – December 2, 2012, Venice, Italy.
- 21) Conference Co-Chair: “Kidney Disease Global Outcomes (KDIGO) Controversies Conference on Heart Failure in Chronic Kidney Disease”, Athens, Greece, May 25-28, 2017
- 22) Chairman, “Cardiometabolic University”, Dallas, TX, December 3-4, 2017
- 23) Chair, American Heart Association Council on the Kidney in Cardiovascular Disease and Council on Clinical Cardiology. Cardiorenal Syndrome: Classification, Pathophysiology, Diagnosis, and Treatment Strategies: A Scientific Statement From the American Heart Association, 2019
- 24) Committee Member, American College of Cardiology, Navigating Treatment Decisions for Patients with ASCVD and Multiple Comorbidities Committee, 2019-2020
- 25) National and International Advisor/Reviewer/Presenter/Contributor for 4D Molecular Therapies, ABC News, Abbott Laboratories, AbbVie, Advanced Health Media, Aegerion, Affymax, Akceia, Akebia, Alere North America, AMAG, Amersham, Amgen, Amylin, AntiSeptiscope, Aralez, Ardian, Arra Hitech, Astellas, AstraZeneca, Astute Medical, Atherotech, BG Medicine, Avenue Therapeutics, Aventyn, Back Bay Lifescience Advisors, Bayer, Biocritique, Bioexpertise, Biomarin, Bionest Partners, Bioporto, Biosite, Biostar, BioZ, Boehringer Ingelheim, Braintree Laboratories, Broeker, Bristol Myer Squibb, Cardiokine, Cardiorentis, Charles River Associates, Chelsea Therapeutics, Chiesi USA, ClearView Healthcare Partners, Clinipace, Complexa, Connected Research and Consulting, CorMedix, Cornerstone Therapeutics, Corvidia, Covance, Critical Diagnostics, Cromsource, Crossover Technologies, Chrysalis BioTherapeutics, Cytopheryx, DaVita, Daws, DeMatteo Monness, Diadexus, Daiichi Sankyo, Decision Resources, ECG Healthcare, Edwards Life Sciences, Elsevier, F. Hoffmann-La Roche Ltd, Fast Biomedical, Fish and Richardson, LLC, Fisher Scientific, FlowMedica Inc, Frictionless Digital, Fresenius Medical Care, General Electric, Genzyme, Gerson Lehrman, Gilead, GVI Clinical Development Solutions, Health Law Partners, Healthspan DX, HealthSTAR Communications, Hershey, Hikari, Hudson Global, ICON, Huff, Powell, and Bailey, LLC, Imidex, Impact Education, Instrumentation Laboratories, Intercept Pharmaceuticals, Intrinsic Life Sciences, Ischemix Technologies, Janssen, Janssen, Johnson and Johnson, Jordan, KAI Research, Keryx, Ketchum, Inc, Knowledge Point 360, Kowa, Eli Lilly, LabCorp, Lewis Brisbois, Liberty Dialysis, Ligand, Lipocine, Litchfield Cavo, Luitpold Pharmaceuticals, Lundbeck, Maxaccess Managed Markets, MannKind, MEDACorp, MedEd Group, Medevera, Medical Exchange International, Medical Package, Medicines Company, Medicure Pharma, Inc., MedReviews, Medscape,

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Medtronic, Merck, Meso Scale Diagnostics, Miller Tanner Associates, Mitsubishi, Nanomix, Nanosphere, Nabi Biopharmaceuticals, Navigant, NephroGenix, Neumedicines, Noorik GmbH, Norman, Hanson, and Detro, LLC, Novartis, NovoNordisk, NxStage, Ortho Clinical Diagnostics, Osprey, Otsuka, Overcome, P-value Communications, Parexel, Pharmapprove, Pfizer, Phoenix Holdings, Physicians World, PLC Medical, Praetego, PriMed, Progenabiome, Quidel Corporation, Qualidigm, Quintiles, Reata, Reliant Pharmaceuticals, Renew Research, Relypsa, Repros Therapeutics, Roche Diagnostics, Rock Creek, Saferox, Saghmos Therapeutics, Salix, Sanfit, Sankyo, Sanofi, Sarepta Therapeutics, Scarritt Group, Sentinel Investment, Sphingotec, Spectracell, St. Jude Medical, Strataca Systems, Statprobe, Synageva, Takeda, Tasly, TheHill, Thrastos, TrialSiteNews, Trinity, Triptych Health Partners, US Medical Management, Vasomedical, Verrow, Vindico, Visiting Physicians Association, Vitalmetrix, Vivus, Watermark, WebMD, ZS Pharma, Inc.

EXHIBIT B



<https://www.who.int/news/item/14-12-2020-who-information-notice-for-ivd-users>

194 captures

14 Dec 2020 – 2 Feb 2021



World Health
Organization

WHO Information Notice for IVD Users

**Nucleic acid testing (NAT)
technologies that use
real-time polymerase
chain reaction (RT-PCR)
for detection of SARS-
CoV-2**

14 December 2020 | Medical product alert | Geneva
| Reading time: 2 min (554 words)

Product type: Nucleic acid testing (NAT) technologies that use real-time polymerase chain reaction (RT-PCR) for detection of SARS-CoV-2

Date: 7 December 2020

WHO-identifier: 2020/5, version 1

Purpose of this notice: To ensure users of certain nucleic acid testing (NAT) technologies are aware of certain aspects of the instructions for use (IFU) for all products.

Description of the problem: WHO has received user feedback on an elevated risk for false SARS-CoV-2 results when testing specimens using RT-PCR reagents on open systems.

As with any diagnostic procedure, the positive and negative predictive values for the product in a given testing population are important to note. As the positivity rate for SARS-CoV-2 decreases, the positive predictive value also decreases. This means that the probability that a person who has a positive result (SARS-CoV-2 detected) is truly infected with SARS-CoV-2 decreases as positivity rate decreases, irrespective of the assay specificity. Therefore, healthcare providers are encouraged to take into consideration testing results along with clinical signs and symptoms, confirmed status of any contacts, etc.

Users of RT-PCR reagents should read the IFU carefully to determine if manual adjustment of the PCR positivity threshold is necessary to account for any background noise which may lead to a specimen with a high cycle threshold (Ct) value result being interpreted as a

positive result. The design principle of RT-PCR means that for patients with high levels of circulating virus (viral load), relatively few cycles will be needed to detect virus and so the Ct value will be low. Conversely, when specimens return a high Ct value, it means that many cycles were required to detect virus. In some circumstances, the distinction between background noise and actual presence of the target virus is difficult to ascertain. Thus, the IFU will state how to interpret specimens at or near the limit for PCR positivity. In some cases, the IFU will state that the cut-off should be manually adjusted to ensure that specimens with high Ct values are not incorrectly assigned SARS-CoV-2 detected due to background noise.

Manufacturers regularly review the design of their product, including labelling and IFU based on customer feedback. In the early phases of the COVID-19 pandemic, in vitro diagnostics (IVDs) were rapidly developed, validated and verified, and then rolled out. Therefore, it is not unexpected that IVDs may require refinement based on user feedback after their introduction at scale. Users should verify the version of the IFU with each consignment they receive to see if any changes have been made to the IFU.

Advice on action to be taken by users:

- 1. Please read carefully the IFU in its entirety.**
- 2. Contact your local representative if there is any aspect of the IFU that is unclear to you.**
- 3. Check the IFU for each incoming consignment to detect any changes to the IFU.**
- 4. Consider any positive result (SARS-CoV-2 detected) or negative results (SARS-CoV-2 not detected) in combination with specimen type, clinical observations, patient history, and epidemiological information.**

5. Provide the Ct value in the report to the requesting healthcare provider.

Transmission of this WHO Information Notice for Users:

Please disseminate this notice to all those who need to be aware within your organization or to any organization where the potentially affected product has been deployed and used.

Contact person for further information:

Anita SANDS, Regulation and Prequalification, World Health Organization, e-mail: sandsa@who.int

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